ETHICAL ISSUES IN SCREENING POPULATIONS FOR DISEASE: FRAMEWORKS FOR POLICY DECISIONS AND CLIENTS’ PERSPECTIVES IN KENYA

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DECLARATION

This thesis is my original work and has not been presented for a degree in any other university or any other award.

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DEDICATION

This work is dedicated to my wife Naomi and Children, Joel and Edwin. Without their perseverance and commitment this work would not have been possible. Also, to those whose endeavor to develop bioethics in health research and public health practice remains.
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ABSTRACT

Background
Screening population for disease is a public health strategy directed at asymptomatic individuals to undergo medical assessments to detect early unapparent or occult conditions. Screening programs may be designed to be compulsory or voluntary. The basic scientific criteria for mounting screening include availability of a valid and repeatable screen test to identify correctly unrecognized or pre-disease conditions; lead time advantage and effective interventions for the target disease.

Aim of the study
We aimed at eliciting participant experiences and latent ethics issues about screening based on content analysis of the data set.

Participants and methods
We reviewed relevant regulatory and policy documents on reproductive health and conducted focus group discussions with women recruited from Cancer of the cervix clinics and antenatal clinics (where maternal Syphilis is routinely screened). Using open codes we extracted, condensed and sorted out themes from the data set by relevant content areas and developed them into conceptual categories for further analysis.

Results
The health care policy approach in Kenya is a utilitarian rights-based user-focused one. Maternal Syphilis and Cancer of the cervix carry high morbidity and mortality, with high incidence among women. Screening is acknowledged as an effective approach to controlling these diseases. Screening for maternal Syphilis is compulsory but opt-in for Cancer of the cervix. The national guidelines on reproductive health stipulate ‘acknowledging informed consent’ during screening; adequate documentation; discussing results and follow up issues with the client. Health providers perceived the screen tests as a widely available and acceptable part of providing comprehensive health care but the national demographic surveillance reports indicate low service uptake. A majority of participants appreciated screening as enabling them to know their status regarding the target disease. A few felt they were coerced into doing the tests while others expressed ambivalence. Key ethical considerations for screening elicited relate to voluntarism, paternalism, coercion, information disclosure, time burden, psycho-emotional stress and test validity.

Key words: screening, ethics, client perspectives, compliance, understanding risk, voluntarism, decision-making, paternalism, harm, time burden.
CHAPTER 1

Introduction

This chapter introduces the concepts of screening and its rationale in public health as well as the inherent ethical issues frequently encountered in designing how to mount screening exercises.

The concept of early detection of disease or its precursors in asymptomatic populations through screening is a noble public health intervention strategy used since the early years of the twentieth century. The benefits include detecting diseases early when treatment is more effective, less expensive or both; identifying risk factors that predispose an individual to higher than average risk for developing a disease; preventing or minimizing disease burden by modifying or eliminating identified risk factors. Screening in health care has been defined as “… a public health service in which members of a defined population who do not necessarily perceive that they are sick of, or are already affected by a disease or its complications, are asked a question or are offered a test to identify those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk of disease or its complications”. The public health justification for a population screening program is early diagnosis that leads to a cost-effective and measurable reduction in disease burden and improved quality of life in the aggregate whole.

Screening programs are broadly categorized according to whether participation is mandatory or voluntary, although this distinction is less obvious in practice. Typically, screening is initiated by the care provider rather than by the individual. It may be sponsored by voluntary private organizations or, more often, mounted by the state / state agencies. Often, it is with respect to the state-initiated screening process that issues of compulsoriness emerge. Because the existence of unrecognized disease is by itself not sufficient reason to screen, it is important to evaluate the efficacy of a given screening approach and assess it for associated harms, before it is considered
for widespread implementation in populations. Ideally, the ethical rationale for the approach used should be demonstrated and deemed acceptable\(^4\). Even so, the intended outcome must be more good than harm.

Ethical decision making in public health practice is often difficult because empirical evidence is inherently complex and uncertain\(^5\) and because of the potential conflict between public health practice, human rights and the legal provisions\(^6\). It is stipulated that screening programs should basically satisfy the following criteria: the disease should be an important health problem; the disease should have a detectable preclinical phase; treatment of disease detected before the onset of clinical symptoms should offer benefits compared with treatment after the onset of symptoms; the screening test should meet acceptable levels of accuracy and cost, and the screening test and follow-up requirements should be acceptable to individuals at risk and to their healthcare providers\(^7,8\). However, these criteria address more of the scientific considerations than the ethical-legal issues.

In Kenya, screening programs are typically enmeshed within the health care system such that clear distinction from routine medical practice is obscured. More often than not, they are state sponsored; occasionally they are mounted by non-governmental organizations. There is no current published audit information on the ethical issues of screening disease in Kenya. The aims of this proposed study are to review the frameworks for mounting screening populations for disease as a public health strategy and to elicit perceptions of Kenyans with regard to the ethical issues in screening. The ultimate objective is to guide the development of public health policies in implementing population screening in a range of health care settings, particularly in low-resourced countries.
CHAPTER 2

Literature review

This chapter provides a critical analysis of the historical background, context and current practice of screening in public health. Specific topical issues relevant to the study are highlighted.

2.1. Historical background of screening in public health

The concept of screening the population for disease as a public health intervention strategy became more apparent in the early years of the twentieth century. It was used by the US army in the early detection of sexually transmitted diseases (STIs) in the USA by early 1900s. Its public health benefits were first demonstrated when in the 1940s it was used to detect pulmonary tuberculosis (PTB) by mass miniature roentgenography (MMR)\(^2\). The first large scale community screening was carried out in Massachusetts to screen for diabetes in 1946–47. Gradually, other screening tests such as neuropsychiatric screening adjunct (NSA) tests (used in the US army), Papanicolaou test for cervical cancer, and mammography for breast cancer were developed and the theory for their conception and interpretation adopted. Often, such screening was mandatory or legislated as a condition for undertaking a desired course of action. For example, premarital screening for STIs was done to protect unsuspecting spouses; pre-school entry screening to protect classmates and peri-/post-natal screening to detect early inborn errors of metabolism to facilitate early interventions. At the same time surveillance was introduced to follow up the individuals; to track patterns of morbidity and mortality and to initiate restrictive measures such as compulsory treatment and quarantine\(^9\).

Nevertheless, the introduction of screening into the public health care soon stirred up debate among both professionals and the public because of concerns on the real benefits of widespread screening. Intrusions on the patient’s body and privacy, protecting patient confidentiality during
follow up, compulsory treatment or confinement, stigmatization and difficult reproductive choices among the minority groups who were more often targeted were the major issues\textsuperscript{9, 10}. In addition, it needed to be distinguished from routine clinical testing using specified criteria to justify it as a public health intervention program. To date these tensions persist\textsuperscript{2, 11, 12}.

In 1961, Thorner and Remein of the public health service in USA published a comprehensive review of the principles of screening for diabetes, in which they discussed the complexities involved in the conduct and interpretation of screening tests. Subsequent authors in the 1960s also indicated the need for an in depth information on the validity and reliability, and their respective predictive values in screening tests \textsuperscript{2, 11}. A landmark paper by Wilson and Jungner in 1968 (published by WHO) defined the key principles and practice criteria of screening for disease\textsuperscript{2}. Current guidelines for screening programs, such as the one by the Council of Europe produced in 1994\textsuperscript{13}, are largely based on these basic concepts. Together, these articles provide the basic concepts for population screening.

Screening programs are to be distinguished from clinical tests. Generally, screening programs are regarded as coordinated public health efforts which use medical test(s) in a systematic manner to achieve specified health goals in well defined target populations. Ideally it is offered as part of a broader disease prevention strategy within the health care system, directed at asymptomatic individuals to undergo medical assessments to detect early unapparent or occult conditions. The entire exercise may be seen as one of successively reassigning people into different groups of positive and negative or high and low risk groups for disease\textsuperscript{21}. The basic scientific elements that simultaneously define screening are the availability of a valid and repeatable screen test (in terms of reasonable sensitivity, specificity and reliability) to identify (or predict) correctly unrecognized disease or pre-disease conditions; a compelling lead time advantage and an effective intervention
for the target disease. Also crucial is the signification of its formal structure, with reference to the ethical-legal and institutional sanctions, and context.

Screening programs may be designed to be compulsory or voluntary. Conceivably, subtle overlaps in program categorizations exist in practice as either group may contain elements of both compulsion and voluntary participation. Therefore, characterizing type of a program may be difficult to achieve. A paper published in 1991 by Faden and colleagues proposed a logical conceptualization of screening programs into five categories, based on the level of voluntariness and notification involved: 1) completely mandatory programs; 2) conditionally mandatory programs; 3) ‘routine without notification’ programs; 4) ‘routine with notification’ programs and (5) voluntary programs.

In completely mandatory programs, citizens are required to undergo the screening by the government agency. Sanctions are imposed for noncompliance. Invariably these are legislated and may be specific or just broadly stated. The underlying principle is social control over individual autonomy. Stringent evidence that only such an approach will result into greater societal benefit, in terms of morbidity and mortality prevention is required to justify its acceptability. Conditionally mandatory screening programs are those which are designated as conditional for one to participate in a service or opportunity. Although the individual has the right to opt out of these services, eligibility for the opportunity depends on participation on the screening program. Restrictions imposed by conditional screening programs, hence the ethical implications may be influenced by the range of needs and of opportunity options available to the participants.

Routine without notification are screening programs that are carried out routinely and automatically implemented unless the individual requests to be exempted. Participants are neither told about it nor of their right to refuse. There is no obligation in law to inform participants of the testing or conditions to be tested for. In this category, the participant is unaware that the screening
is being done and is therefore restricted in making any choices. *Routine screening with notification* are carried out only after the participant is informed / notified of the intervention intended. In *voluntary screening programs* participant authorization is required before implementation of the service. However, neither of these last two categories guarantees that participant choices will be voluntary, because of the possibility of manipulation, coercion, inadequate information and understanding. In Kenya, various screening approaches are implemented routinely or automatically in the various departments during patient visits without necessarily notifying them. For example, screening for cancer of the cervix is currently being promoted and carried out as an outpatient procedure to consenting females. Some of these clients voluntarily come to be screened while some of them are referrals from other outpatient clinics. Screening for Syphilis antenatally is required for all pregnant mothers at their first visit. Blood specimen is collected by the attending nurse and taken to the laboratory. The laboratory technician returns the results to the nurse when ready. Notification or consenting for the screening process is not commonly practiced.

Typically, implementation of screening in a culturally diverse community is particularly challenging. Overall, the magnitude of the ethical issues associated with participation of populations is liable to be aggravated by the compulsoriness of the programs. Consequently, a critical ethical analysis of a screening program would be necessary, considering both the formal structure of the program (in terms of attributable legal or institutional restrictions) as well as utility and equity issues within the Kenyan context. The perspectives of the public health model is often adopted for this moral and value analysis. In the public health model, the principal goal of the government is to secure the aggregate health and safety of the majority of the public by preventing occurrence of morbidity and mortality\(^3\).
2.2. Philosophical concepts of screening

By convention, ethical considerations on screening as a public health intervention largely are derived from the bioethical theory. This theory constitutes the descriptive, normative and the metaethical concepts that define the ideals of our morality, namely the rights, obligations, virtues and values\(^{10}\). Traditionally, the particular methods of ethical decision-making were based on either the consequences expected (teleological) or the nature of the action itself (deontological). Teleological – based ethics determines the worth of an action by the aggregate results it produces, regardless of the nature or process. The principal goal is to maximize utility. Conversely, deontological ones determine the actions independent of the consequences, the emphasis being on the rightness of process\(^{14, 15}\).

The contemporary submissions tend towards a mixture of the two approaches: attending to ‘rightness’ of an action in terms of its nature and process, and the ‘intrinsic goodness’ of it in terms of what is accomplished\(^{14}\). The advantage of this approach is that the best moral act will attend to the traditional norms / values and will achieve agreeable results, at the same time both the process and the consequences are considered together. However, still it does not provide a decisive method to resolve an ethical dilemma incurred in planning screening interventions\(^{16}\). Furthermore, it has been argued that the bioethical theory lacks a concrete moral philosophical base which makes the translation of the ethical theories into biomedical practice problematic. Also, a clear cut link to population health practice (as opposed to medical practice) is not easy to establish. Accordingly, there is a tendency towards an interdisciplinary approach to derive operational principles from law, public policy, empirical studies and standards of practice, government and international guidelines\(^{15}\). With the recent emergence of public health ethics as an independent area of study, proposed new frameworks for screening have to be debated and redefined based on considerations of utility (in terms of net benefits), equity, respecting civil liberties, minimizing harm, and partnership with the target populations\(^{16, 17, 18}\).
The ethical-legal principles of public health, of which screening is a part, hinge on its societal approach to protecting and promoting health. The government in its representative capacity is the only one authorized to act on behalf of the public. The police powers are the constitutional authority on which public health measures are based\(^\text{19}\). The key ethical decisions mainly concern standards and structure for health protection and promotion (framework for rights), priorities for programs (utility) and health resource distributions (equity)\(^\text{17}\). A state’s failure to recognize or acknowledge health problems that particularly impact on marginalized or vulnerable groups may both violate the right to non-discrimination and also lead to neglect of health effective interventions\(^\text{20}\). Conventionally the moral approach to public health practice is a consequentialist notion, which clearly advocates making the total benefits as large as possible to the largest majority, while keeping the total burdens as low as possible. Accordingly, a greater societal good is achieved by minimizing threats to health\(^\text{9}\).

### 2.3. Analytical frameworks for population screening

The global aim of public health is to secure the greatest good (that is the best level of health: considered as normal functioning) to the entire population. Screening has the potential to improve quality of life, to prevent the development of disease, disability and to prevent premature death. Nevertheless tensions inherently exist in its design and implementation. It is in this interface that harm to the population may occur. Harm is here defined as actions that reduce physical and / or psychological well-being\(^\text{23}\). For example, the moral obligations of the government to protect, provide and secure health and safety to its citizens may also contradict their autonomy to use these services, either by restricting or compelling their actions through the intervention. Identifying a section of the population on the basis of their disease status or as a risk group may also tag them, hence a cause of potential for harm due to discrimination.
Essentially, screening plays a ‘gatekeeper’ role of preventing others from coming into harm. Also it is considered to enhance autonomous decision-making. The ethical value judgment of screening hinges on these two major concepts\textsuperscript{24}. The implementation and implication of the twin-pronged conceptions is the subject of much debate. According to Erich Loewy\textsuperscript{25}, the interplay between individual liberties (autonomy) and the benevolent actions of health interventions (responsibility) should be considered as a homeostatic balance rather than a ‘conflict’. Consequently, the appropriate action is one that would create and maintain a reflective equilibrium between the aggregate of individual goods and burdens. This is achieved through right policies that assure maximum benefit at a reasonably minimal burden.

Although the public health model is paternalistic in nature, it does not knowingly harm the minority. According to the harm principle proposed by Stuart Mill (1806 – 1873) the government is morally justified to prohibit actions that will cause serious harm or high risk to others and in requiring actions that prevent harm. Mill’s method of assessing risk or level of public welfare attributable to a given action is by ‘competent judgment’ or ‘expert opinion’. But this is viewed by some postmodernists as an overbearing view on the society. The expanded version by Joel Feinberg indicates that these harms must reach a minimum threshold before they are prevented. He categorizes harm into two, namely private and public harm. Private harm holds that liberty can be restricted to prevent harm to specific individuals or groups, while for public harm liberty can be restricted to protect society from harm. Alternatively, paternalism is morally justified in imposing restrictions or requiring preventive actions on an agent for his or her own good, even if no one else will be harmed\textsuperscript{9, 23, 26}. Paternalism is premised on the concept that individual rights in autonomy, privacy, liberty and property do not trump over community tenets. It also assumes that in public health practice, health is considered as a special kind of good in the economy.
Rights implied by the principle of mutual respect are interpreted in two different ways. Libertarians believe that only negative rights deserve protection. These rights guarantee individual freedom of choice unrestricted by state agencies. By contrast, egalitarian liberals emphasize on the rights that guarantee a minimum level of services and resources (such as minimal standard of health care: this implies a redistributive perspective of health which favors more the groups that are worse off in order to improve their range of opportunities when they make life choices). Therefore the government’s concern for the communal health welfare justifies interventions (even though that may impose harms on individuals themselves and only on others secondarily). Some commentators however, argue that there are no special rights to health or health care. Instead, what is critical is redistribution of resources and information to facilitate the capacity of individuals to chose and purchase the health care they need. The only role of the state would be where markets fail for technical reasons. Still, others contend that the liberal state should make health care available to its citizens (which would maximize their capabilities) but leave it to them to be responsible for their own behavior and use of the care that determines health status.

On the other hand, for communitarians the focus is on creating a good society and producing right individuals for it. This aristocratic perspective is hierarchically defined, where individuals fulfilling their specified roles in their right places are counted virtuous. But the question is who decides what a virtuous conduct is? The relativist communitarian sees morality as inherently contextual (with respect to community’s tradition) with the implication that no restriction is necessary. On the other hand, the universalist communitarian believes in a single true form of good society and its associated virtue. In public health this translates into restricting adverse lifestyles while promoting positive ones and interventions that would improve health, regardless of cultural norms. These are justified on the basis of their health consequences or as a matter of rights. However, the level of limitations is not defined by these theories. A postmodern approach holds that the rules for judging moral arguments are based on the rules internal to the enterprise, but
those rules cannot be derived from more fundamental principles, although this does not mean that all moral views and actions are compelling\textsuperscript{27}.

A more pragmatic approach is needed to make health a universally accessible good with adequate decision options to facilitate health choices: the implication is that a single ethical theory may not suffice in resolving the ethical issues in public health practice, hence the need for multiple viewpoints\textsuperscript{27}. This may help in defining appropriate theoretical concepts for designing and implementing screening programs. The challenge then is to defend the mixed positions adopted for the defined intervention approach.

Paradoxically health is both individualistic and public\textsuperscript{28}. Ultimately, the main issues are how to interpret individual rights \textit{vis-à-vis} the broader societal health goals; decide on what should be the decision criteria for the minimum standards of health and health care over time and what sort of screening options should be employed to detect early preclinical disease and / or their precursors. The implication for the public health decision-making is to distinguish between health as a prerequisite for choice and health as a consequence of choice, which raises an ethical dilemma in terms of designing the structure and process of delivery (implementation) of screening as an intervention to compress morbidity and reduce mortality in the community. The chosen public health policy will offer guidance on how to look at the twin demands of limits and aspirations by providing a general direction of thought and action, and a basic framework for decision-making\textsuperscript{27}.

As the possibilities for screening increase with use of more advanced diagnostic techniques, so will be attendant ethical problems. Ethics issues such as balancing the prevention of harm from disease against the possibilities of social stigmatization of carriers or discrimination in employment; balancing public health concerns against the rights of individuals as well as balancing the rights of third parties, such as employers, insurance companies, or relatives against the individual's right to privacy will require a more pragmatic approach. The history of screening
for sickle cell carrier status in the United States of America highlights these as yet unresolved dilemmas. In Kenya revelations to having a chronic disease such as cancer of the cervix have adverse implications on the insurance premiums, while having a sexually transmitted infection such as a Syphilis may be stigmatizing at the place of work or at home. Clearly, ethical views of diverse groups including medical practitioners, scientists, lawmakers, and the public are essential to establish regulations for the conduct of screening and access to / use of test results. The objective of regulation in public health is both to prevent unreasonable risks to public health and safety and to ensure equity or resource (re)distribution. However, in Kenya there has been no systematic study of the ethical issues related to the screening approaches. Invariably, an assessment of the screening programs necessarily adopts the public health model for disease prevention. The public health, legal and ethical frameworks for assessment of screening a population for disease as discussed by Faden and colleagues have been adopted for the purposes of review in this study.

2.3.1. Public health framework

The promotion and protection of public health is one of the oldest functions of government. The approach is based on the utilitarian concept. It aims to promote human welfare and reduce human misery and is solidly based on empirical evidence. However, such evidence is often fraught with complex and uncertain outcomes. Also, it is limited by the deontological (Kantian) considerations, such as respect for persons and their rights. The critical question arises when individual interests and rights conflict with the state’s interest to promote and secure public health welfare. The process of a public health enterprise “involves public officials taking appropriate measures pursuant to specified legal authority, after balancing private rights and public interests, to protect the health of the public. These measures may be coercive.” Government regulation of any type necessarily implicates the discipline of administrative law – a discipline concerned with the
procedures by which agencies of government discharge their statutory responsibilities and reviewing courts oversee the legality of agency actions. The legislated legal authority must offer reasonable regulations and clear guidance on the limits of the design and powers of public health agencies; delineate the procedures by which they exercise these powers; define the scope and implementation procedures to ensure fairness in protecting the public health and safety; and determine the sanctions / remedies for any unlawful actions by the implementing agencies. 

Nevertheless, government regulation of any type necessarily implicates the role of administrative law – a discipline concerned with the statutory roles of and actions by government agencies (procedures and legality or substantive context).

The utilitarian calculus of the risk to benefit ratio envisaged by the public health model is based on the concept of maximizing (predicted) outcomes from the instituted interventions. (The benefits and harms are understood in terms of the community’s morbidity and mortality). The premise here is that the right action also maximizes the good outcome or utility. This is predicted from the relationship between the benefits and the risks inherent in each of the actions intended. Therefore, the ‘right’ thing to do is the ‘good’ thing to do (where good refers to the intrinsic good). Utilitarianism is also egalitarian in so far as it holds that everyone’s satisfaction is to be considered equally.

To assess which of the available screening action or policy options would produce the highest degree of public health utility / welfare, the risk–benefit estimate for each alternative is made. However, the possibility that the best alternative could conflict with other values, such as fairness, liberty, autonomy, equality or honesty, remains. Secondary (utilitarian) principles to cushion the chosen actions from injustice would therefore be complementary. For example, compulsory screening may be over-inclusive, thereby ignoring the status of the minority who are not at risk for the target condition for screening. But it may also exclude or over-include people with recurrent
risks, depending on the criteria for inclusion and follow up. Should people be compelled to participate in genetic screening or even abortion, for example to reduce the number of babies born with potential vulnerability to cancers? Such a policy would reduce the cost of caring for such individuals and might be rational from the utilitarian point of view. Even though such a policy would promote the greatest happiness to the greatest number, it would nonetheless be morally unacceptable in view of the inherent worth of the fetus. Also, screening should only be acceptable if it could achieve a positive change that would not otherwise be achieved. The degree to which it attains this goal depends on the prevalence of the target disease, the validity and reliability of the screening test, availability of effective treatment and follow up interventions.

The questions of whether we have a duty to be healthy (self-regarding or bearing personal responsibility for our ‘healthiness’) and whether we have an obligation to society to be maximally productive (an other-regarding responsibility) are warranted for consideration in assessing approaches to population screening programs, particularly when they have a high degree of compulsoriness. As self-regarding or ‘role-responsible’ agents, the individuals’ actions towards their own health are critically important in shaping health policy and intervention decisions, for example, in terms of costs and levels of interventions required for the specific population groups. It may be that, the people most vulnerable should acquiesce in programs designed to promote and secure their health. Or it could be that the community as a collective agent may legitimately pursue its collective health goals, even if doing so may conflict with the private goals of some of its constituents.

Alternatively, the rationale for apportioning responsibility for healthiness, thus justifying paternalistic intervention approach could be based on the fairness principle: those who risk illness by unhealthy lifestyle, thereby unfairly burdening others are apportioned liability for their actions. Consequently, the community imposes an obligation on the risk group to submit to the
interventions designed to minimize or prevent further morbidity and mortality in their context. The assertion here is that the individual’s liberty is restricted in order to produce benefits both to himself/herself as well as to maximally protect the larger group to which he is only a small part.\(^{32}\)

### 2.3.2. The ethical framework

Screening for diseases is a complex process that is poorly understood by both professionals and public for various reasons. Ethical issues particularly arise from the way the structure and process of the program is approached, and the potential outcomes related to the process and the procedures used\(^2\). The people involved include those affected or considered affected and / or at risk of disease to be considered for screening; members of clinical staff who will administer the screening tests and give results, conduct counseling and keep information received / notify diseases where indicated; and policy makers who are responsible for national surveillance: processing, archiving, interpretation and translation of the information into public health policy.\(^{33}\)

The ethical dimension of screening as a public health enterprise provides the philosophical knowledge and the analytical reasoning for review and decision making. In addition, it informs on meaning of professionalism and practice; moral weight and value of a community’s health and well-being; guidance on the recurrent themes of the field and dilemmas faced in daily practice of public health and guidance on the role of advocacy to achieve the goal of a healthier and safer population.\(^{10, 34}\) However, there may be moral considerations that conflict with public health objectives. Some of these values may have been given attention within an existing legal framework and others not. Consequently, moral considerations not protected by laws must be balanced against public health interests. The decision maker faces the choice of pursuing either the subjective or objective benefits; total well-being or only medical benefits; which screening goals deserve priority and how to aggregate the estimates of the consequences for optimal decision-making.\(^9\)
Principally, staff are to be guided by their moral and professional codes, and the existing statutory, procedural and ethical provisions for screening a population for disease.

The dimensions of the ethical framework are applied broadly to screening programs to assess moral problems surrounding policies of participation. The diverse and complex bioethical theory falls broadly into four levels of moral discourse: casuistry; rules and rights (codes of ethics); normative ethics and metaethics. A reflective equilibrium within this spectrum of moral discourse is needed when considering the ethical dimensions of screening populations. Three broad moral principles of beneficence, respect for persons and justice, which provide the basis for most bioethical analyses are addressed for the purpose this review, albeit not sufficient for analyzing public health ethics issues.

**Beneficence**

The principle most closely related to the goals of public health and by extension screening programs, is beneficence. It closely focuses on human welfare or well-being. It entails doing good, avoiding harm and balancing benefits and harms. The benefits sought through public health measures is the welfare of the community (reducing morbidity and mortality). These are the welfare objectives that provide the justification and context for public health and medicine. Public health as a good can be seen as a means to achieving societal welfare. In the process benefits and / or harms may be incurred either to the individuals or to whole communities.

Types of risks associated with screening may be physical / medical; social; psychological (anxiety, hope); risks to personhood; monetary or material inconvenience. For example, screening carries an implicit premise to do good, which is to detect disease or risks early and thus improve the diagnostic and intervention outcomes. However this may not always be realized because of uncertainties in the disease course, potential problems such as lead time and prognostic selection bias, the fallibility of the screening tests as well as the uncertainties inherent in the management of...
chronic conditions. For example, less rigorous laboratory tests may require repeat tests, which may impose both psychological harm and moral distress to those with positive test results, or false hopes for those with negative test results but actually have the disease. Additionally, problems of over treatment for those with positive results may occur. Some tests are invasive and may require special expertise to carry out and interpret results. These may be justified when incremental benefits can be demonstrated. But this may be difficult to objectively obtain as accrual benefits may take long to demonstrate, as has been demonstrated with mammography and colorectal cancer screening. Stringent limitations may thus restrict access to the tests for some sections of the society thereby exacerbating social inequities if not well regulated.

Screening may reveal a higher propensity for some illnesses in individuals, families or a larger community which may be interpreted as being universally predictive of the group. Such information may be used by employers, insurance agencies or educators to discriminate against those individuals or community groups thus limiting their access to services. But this may also demean or undermine their personal and social status. Reproductive choices based on screening results may often cause undue psychological pressure. Use of predictive information, as in genetic screening, may be more harmful than beneficial hence the need for more stringent oversight. The potential for loss of genetic privacy may require legislative regulation.

The principle of assessing benefit and harm is known as utility, which holds that an action is morally right insofar as it increases net utility which means taking into consideration the harm that may be also. The number affected adversely by the screening test per thousand or per life saved has been used as an important indicator of benefit. The ethical challenge is to objectively determine and interpret these outcomes.
There is no reason to assume that the value judgments made by the community or the government agency are the correct ones. Maybe the government places more weight on reducing overall morbidity or its consequences and hence, judge the side effects of the interventions on individuals (or sections of the community) less harmful than others in the society. The legitimacy of group or categorical standards for limit setting rather than individualized decisions, and the moral rights and obligations of the caregivers, community and administrators may also pose formidable ethical dilemmas, particularly for value-based decisions. Critical questions therefore arise on what objective standard(s) would be appropriate in deciding what the effects of the screening tests will have on the participant – in terms of the costs or burdens she has to incur during screening process like psychosocial stress, time burden, pain and discomfort and repeat tests; and the next regards how to make judgments about the value of the expected outcome.

The duty to promote the public’s health as an intrinsic good potentially incurs high responsibility in moral life. This may imply that, for example, those who are owed duties of beneficence need to bear some of the burdens related or consequent to the interventions. But the question is how to determine this group to whom duties of beneficence are owed: specific patients; communities / parties; current or future populations. Also the issue of whether it will be possible or right to impute such responsibility at all is debatable. This has further ramifications on the scope and choice of screening.

**Respect for persons**

This implies respect for the dignity, privacy and confidentiality of an individual, simply by virtue of their being human. Basically, it emphasizes on the importance of the individual freedom and choice, both for socio-political life and individual development. The Kantian reference is to a rational self governing individual, free from external interference by others and from personal limitations that impair choice. The implicit premise is that the autonomous agent possesses an
intrinsic value independent of special circumstances that confer value. They are ends in themselves, capable of determining their own destiny and are not to be treated merely as a means to an end. Consequently, they should be free to choose and act without controlling constraints imposed by others. This provides the justification for autonomous decisions and informed consent to allow interventions. Most of these are largely expressed as specific autonomy-related rights and obligations\textsuperscript{43}. Respecting patients’ autonomy presupposes the presence of autonomy in sufficient degree; however, not all patients are sufficiently autonomous.

The current perspective suggests that biomedical practice should espouse as a priority a shared vision of human dignity that reaches beyond the individual. In this sense, human dignity is conceived either as empowerment (particularly that which comes with the right to respect for one’s dignity as a human, and the right to conditions in which human dignity can flourish = claims of autonomy) or it can be conceived as a constraint on free choice (by virtue of being a collective good that represents each society’s vision of what kind of society it wants to be = claims of other social values)\textsuperscript{44}. The balance of the two conceptions (or prioritization of either) has implications on the translation and application of decisional authority in bioethics practice.

Critiques against screening point to its tendency to compulsoriness and lack of adequate disclosure of pertinent information across the spectrum of screening programs. But these choices may at times conflict with other values. Moreover, the scope and limits of the principle remains unsettled. In some cases when autonomous choices might endanger public health, harm the fetus or involve a scarce resource for which the individual cannot pay, it may be justifiable to override the individual’s choice and impose statutory restriction. If the restriction is in order, then justification rests on the competing moral principle such as beneficence or justice\textsuperscript{10}.

An alternative account of autonomy can be characterized as (1) \textit{procedural} (versus substantive): the client’s decision-making is based on a broader consideration of her beliefs, values
and goals or other considerations such as emotion, inclination, opinions of significant others who may influence their choice process. (2) Decisional (rather than executional): this is based on relational factors within a given socio-cultural domain that affect personal decisions. (3) Contextual and interactive (versus abstract and individualistic): the client’s autonomous decision-making may be modified by her prevailing interdependence in the given environment. (4) Decision-specific (as opposed to global or general): the patient’s decision “is understood as a feature of some aspects of her life” rather than a considered aspect of her “entire life”\textsuperscript{45}. However, this conception of autonomy must be interpreted in terms of communication factors that surround the client - physician relationship and the broader structural and systems context.

The concept of informed consent is based on the principle of respect for persons. The process of obtaining informed consent is an expression of respect for the person’s dignity. It is intended to equip the individual with the knowledge needed to make a rational choice and to remind the physician of the duty to apprise the subject of the potential risks however subtle or remote. This includes providing the patient adequate information to support post test/intervention compliance and self-monitoring as well as diminish inaccurate fears and misconceptions about their situations and prospects\textsuperscript{45}. Besides, it extends to a legal requirement where an invasive test is involved. The clinician should be fully aware of the range of risks to persons they test or recruit for testing. This awareness will also facilitate appropriate design of the screening process that minimizes the potential for harm while maximizing disclosures to allow the participant to make a rational decision\textsuperscript{42}.

The communication should be accurate, simple to understand and appropriately conveyed. Information is most effectively conveyed verbally by a health professional, supplemented and reinforced by written information or other communication aids\textsuperscript{46}. These can be simply and effectively administered in any screening context. The ultimate aim is to elicit a genuine consent
rather than merely executing a routine process. The limits and capacity of the participant to understand and deal with difficult information should be appreciated; hence, the scope of the information ought to be related to the context of the individual participants. Those with diminished cognitive capacity to consent, such as the children or mentally retarded should have a competent surrogate for the process (although this too has its own complexities). However, the client’s autonomy must still be supported by giving them the right information, even when the tests are offered in their best interest. Children should only be tested when it is in their best interest and when effective intervention or treatment is available.

Enabling informed choice in screening is a complex process that needs careful consideration. High rates of uptake of and yields from screening programs should be attained in order to achieve a significant population impact in reducing mortality and/or morbidity from a disease or condition. However, participants must still be allowed to make an informed choice or decision on whether to be screened. Consequently, tensions arise between promoting informed choice, where the individual may choose not to undertake screening, and promoting effective forms of screening. It has been argued that in order to make an informed decision about whether to participate in screening, an explicit sharing of information about the risks and benefits is required. An appropriate framework for disclosure and consenting in a screening set up would include: (i) privacy guidelines in order to protect the client’s confidentiality; (ii) a description of the range of the tests and the alternatives available; (iii) a description of the levels of health care where these options are obtainable, their rationale and competencies of the professionals to conduct the tests and disclose the results; and (iv) archiving the participants’ results and the distribution of these results if need be for public health responses, academic or commercial purposes. Specific information would include the following: the purpose of the screening; the likelihood of positive and negative findings and possibility of false positive/negative results; the uncertainties and risks attached to the screening process; any significant medical, social or financial implications of
screening for the particular condition or predisposition; and follow-up plans, including the availability of counseling and support services. However, the impact of this information sharing on screening uptake is unknown.

The problems inherent in information disclosure and taking of consent in screening population for disease include the following: (i) whether consent should be written or verbal; (ii) dealing with cognitive incompetence; and (iii) risks and benefits of a given test may never be fully known whether in the short term or in the long term. For example, some tests may simultaneously reveal or expose conditions for which there is no effective intervention or may be costly to ameliorate; in some cases the disorders are heterogeneous while some may involve difficult reproductive choices, or are just indolent ones as may occur with some of the screening tests for Cancer of the cervix; (iv) benefits may be specific or non-specific; (v) sensitive biological information, such as non-paternity of individuals or fatal conditions; (vi) legal liabilities, for example, whether tests should be routinely performed where a range of them are readily available coupled with issues of the client’s right to be tested and the right to know; (vii) obligation to share information with the relatives of the client or other third parties. In nations without national health insurance, governments must decide how to prevent discrimination by insurers and other third parties on the basis of (genetic or other) information from screening. Access for family members, especially those at genetic risk, presents complex ethical problems that may be resolved differently in different cultural settings, but should be the subject of further international discussion.

Information disclosure when seeking consent or giving test results in a given context may at times entail a difficult ethical dilemma, in terms of the right-to-know or a right-not-to-know between the individual and the relatives or employer (who undertakes the screening). A pre-symptomatic test, given early enough, may permit potential victims to plan for both their lives and
their families even if it does not lead to a better prognosis. On the other hand, it can potentially lead to depression, stigmatization, and loss of economic benefits. Also it may be difficult to predict an individual’s response or to determine the right balance in order to avoid harmful anxiety. Conflicting principles of privacy and confidentiality and the respect of other persons on the one hand and non-maleficence on the other may pose a difficult ethical or legal question in handling sensitive information that carry a public health implication. For example, screening involving minors or adults with inadequate decisional capacity requires the presence of surrogates for consent. Although individuals may have access to their test results, the pertinent question is whether those at significant risk should be informed of their results even if they do not wish to know them. Also, the question of how far to pursue screening tests in order to satisfy one’s right-to-know is not always easy to determine, especially where tests are routinely available.

**Justice**

Justice refers to the fair distribution of resources, benefits of intervention innovations and burdens of disease intervention. To this end, judgment of what is due, fair or owed to a group(s) is essentially comparative. It is a term used widely to refer to what is legally or morally right, that which allows choice (as opposed to mandatory programs) or to proportionality in conferring obligations and rights as well as benefits and risks, for example in responding to specific disease patterns. For instance those who are most vulnerable to a disease pattern either due to their social context or genetic make up / environmental exposure may be targeted for screening programs with high levels of compulsoriness or they may be apportioned a higher burden of the screening procedure. This principle is usually applicable in decision making with regard to targeted screening for high risk groups. However, there is an interplay between this principle and the other two discussed above, though it must be decided which (if any) moral principle has priority. Note that no moral principle has any absolute stature that allows it in every occasion to
override conflicting moral claims. Therefore, the criteria used in each case must always be explicated\textsuperscript{3, 53}.

2.3.3. **Legal framework**

The design and conduct of a screening program ought also to conform to the national legal provisions: constitutional requirements, common law, statutory provisions and ethical codes. Conceivably, framing, interpretation and application of the laws and ethical codes would consider a balance between the civil liberties of the individuals tested and against that of the public health goals\textsuperscript{3, 6}. A finding that a given law conflicts with a right that is constitutionally protected usually raises another consideration: how important is the interest that the government is advancing, and how significantly does the law impinge on the individual rights in question? Only extremely important government interests – often described as ‘compelling’ – are likely to prevail in such situations, and only when the law is written so as to minimize its effect on the constitutional right. However, decision making on the ‘compellingness’ of the government’s intentions and the scope of its powers is far from straightforward\textsuperscript{8}. Problems logically arise before, and to some extent apart from, a full consideration of the policy issues relating to what we might want a government to do in a particular situation. The Kenya Public Health Act of 1986 gives broad powers to the public health agencies to implement public health goals. But when can the protected civil liberties be overridden? The ethical-legal framework and the necessary instruments to aid effective decision making in such circumstances are either less explicit in the available legal tiers, or are poorly understood by the professionals.

The legal provisions – both procedural and substantive ones – that guarantee protection of the diverse individual interests include protection against undue infringement of personal liberties; protection of the individual’s right to privacy against unwarranted search, seizures and disclosure of sensitive personal information; right to make certain medical decisions without undue influence
from the caregiver and protection against discriminatory treatment. The courts may examine, evaluate and interpret provisions for the screening programs in terms of its legality as implemented, outcomes and access to and, use of data from screening. The caregivers are also guided by their professional codes of ethics, which define standards and regulate professional practice.

Legal challenges to screening programs may arise due to practices by the state or private institutions, for example, where it is deemed to restrict or infringe on the individual liberties. Also provisions on financial and regulatory requirements for private institutions may subject them to constitutional duties and standards of conduct. Legal issues in screening include objection to compulsory screening as an infringement to the person’s bodily integrity and to privacy; targeted screening which singles out persons to be tested carries potential for discrimination; mandatory with the possibility of over-inclusiveness, as in mass screening involving a high degree of compulsoriness of participation. Currently there is no literature available on the ethical-legal framework for public health interventions in Kenya.

2.4. Criteria for resolving ethical dilemmas in screening populations for disease

The following elements, which constitute the framework as proposed recently for resolving ethical dilemmas in public health ethics, are similarly applicable in screening practices:

1. Effectiveness: the ability of the program to achieve its designed objective for screening of Cancer of the cervix to be effective in a population, a large number of healthy individuals have to be tested, but this may imply huge cost investment. This can only be justifiable if the goal of reduced morbidity and mortality among women is achieved without simultaneous over-diagnosis and over-treatment;

2. Proportionality: the societal benefits of the intervention that must outweigh risks or infringement imposed by the procedure on the target group. For example, the release of
surveillance data on Cancer of the cervix and Syphilis should lead to proportionate release of resources for appropriate interventions to populations with the highest disease burden;

3. Necessity: test procedures which though effective and proportionate but impose more risks and infringement on the individual’s / group’s liberties will need compelling justification and more stringent requirements to implement. In Kenya, Syphilis is still endemic with a high incidence rate. The potential for severe adverse consequences of maternal Syphilis to the fetus, mother and partner(s) in the transmission network for a disease that is highly treatable\textsuperscript{54, 56} renders antenatal screening justifiable. Also, the high incidence of Cancer of the cervix among HIV sero-positive women is a public health concern\textsuperscript{58};

4. Least infringement: the best criteria for choosing the right action is to go for the least restrictive on individual’s liberty, least intrusive on their privacy and similarly disclosures which minimize potential risk on confidentiality. Inherently, risks are defined and characterized both scientifically and in terms of the societal context. Both Syphilis and Cervical cancer are associated with sexuality, and social status may incur harms associated with loss of personal and social esteem, stigma, anxiety and fetal loss, among others. Issues of privacy and confidentiality are critical for consideration;

5. Public justification: ideally the chosen intervention / procedure should befit the intrinsic societal goal of protecting and promoting health effectively. Public perception and inputs should be considered in such propositions, without ignoring the positions of the worse off minority. Accordingly, transparency about decisions (including re-evaluation rationale for these decisions) and fairness is essential to ensure public trust. There is need to consider local needs and contextualize policy making process for reproductive health services in Kenya, which guides public health interventions for Syphilis and Cancer of the cervix.
2.5. Background of screening for Syphilis and Cancer of the cervix as a public health strategy in Kenya

Reproductive Health Services (RSH) and related policies, norms, standards and guidelines have evolved gradually in Kenya over the last four decades. The programs aim to improve maternal health, reduce neonatal/child mortality and morbidity, reduce the spread of HIV/AIDS and promote empowerment of women. The key changes have been motivated particularly by the recommendations in the global health scene. There is little information on local evidence on which to base screening intervention approaches, neither are there clearly spelt out methodology on how to implement such screening programs. The National Reproductive Health Policy only provides broad a framework for action regarding planning, standardization and monitoring and evaluation of reproductive health.

The Maternal and Child Health (MCH) program was initiated before 1967 while the National Family Planning (FP) Program was launched in 1967. In 1974, the two programs were integrated into MCH/FP. After 1994, there was a major shift in policy from simply focusing on MCH/FP services to a comprehensive reproductive health (RH) program, which is a broad-based approach to sexual and reproductive health care. The current program is guided by the National Reproductive Health Strategy for 1997 – 2010, its implementation plan (1998 – 2003) and attendant national guidelines. The strategy is largely based on the recommendations of the Program of Action of the 1994 United Nations International Conference on Population and Development held in Cairo which among other development issues emphasizes comprehensive and quality reproductive health services as being critical policy action points. Also, it calls for the implementation of plans emphasizing the strategic roles of information, education and community mobilization and participation, both at decision making and implementation levels. The Norms and Standards for Service Delivery of April 2006 spells out expectations for care at each level plus the
resource inputs that needs to effectively, efficiently and sustainably offer specific service package. However, the inadequate access to these national operational documents is a constant challenge.\textsuperscript{55}

The aims of the Safe Motherhood Initiative which was launched in Kenya in 1987, is to reduce maternal morbidity and mortality through comprehensive preconception care, antenatal and safe delivery services. Clients are provided with education and care to ensure prevention or early detection and prompt effective management of diseases or related complications. It is stipulated that antenatal mothers will make a minimum of four clinic visits before term. Serological tests for Syphilis, alongside hemoglobin, blood group, rhesus and HIV tests were integrated into the antenatal care services in 1989 as the basic tests to be carried out during pregnancy.\textsuperscript{54, 55}

2.5.1. Screening for maternal Syphilis

It is estimated that the prevalence of antenatal syphilis in Kenya is 3.8\% and more than half of these develop adverse obstetric outcomes.\textsuperscript{56, 57} Screening for maternal Syphilis is part of a public health effort to control its spread in the population; mitigate the high risk for adverse obstetric outcomes as well as congenital fetal syphilis among majority of mothers who are Syphilis sero-positive. Organizationally, the Reproductive Health program is implemented and supervised from the District healthcare level, in close partnership with the local community while the National level provides the budgetary and technical support.\textsuperscript{55}

2.5.2. Screening for Cancer of the cervix

Cervical cancer is an important public health problem particularly in developing countries because of the high morbidity and mortality burden associated with it. It is a preventable disease, and currently screening is acknowledged as the most effective approach for control. In Kenya, it is the most common cause of reproductive tract cancers.\textsuperscript{55} Control of cervical cancers through prevention, early detection and effective management is a major component among eight key program areas in the National Reproductive Health Strategy. The national guidelines stipulate that
before the procedure is carried out, “adequate reproductive health history should be taken and recorded and informed consent acknowledged. After the procedure the results shall be discussed with the client and she may be asked to return any time for advice, re-screening or care”\textsuperscript{58}. 
CHAPTER 3

Rationale for the study

3.1. Statement of the problem

Kenya has had a health care system characterized as a less coordinated hospital and community care with less defined boundaries. Health reforms face the difficulty in attempting to achieve full organizational and functional integration of hospital, primary health care and other services. The National Health Sector Strategic Plan II (NHSSP II), launched in 2005 is operationalized through the Kenya Essential Health Package (KEPH). Its plan of action focuses on the life-cycle cohort observation and monitoring within a decentralized health care system. The core policy approach is a rights-based (with a utilitarian tilt) user-focused one. The policy goals aim at assuring the dignity and worth of every person; minimizing social and health inequities as well as improving morbidity and mortality outcomes through institutional reforms to ensure a more structured approach to dealing with health threats. However, the extent of realization and proportionate impact of these changes in public health practice and system reforms is not known. Also, there is lack of up-to-date information on the ethical issues related to screening for the commonest causes of maternal morbidity and mortality in the country. We considered in this study how clients undergoing screening for Cancer of the cervix and maternal Syphilis during antenatal care visits perceive these services. Also we considered the ethics issues related to design and implementation process of these screening programs.

By instituting prudent interventions to reduce morbidity and mortality, the years of healthy life lived by the people at risk could be increased markedly. Ethical issues have a bearing on the outcomes of these interventions in terms of how the public perceives and uses them. However, there is little contextual experience in policy and regulation of specific screening programs as part of public health care interventions with regard to the varied contemporary ethical issues.
This would help to guide attention to the ethics of screening as a public health intervention. The study will focus on the outcomes of continuing screening programs for the above indicated tracer diseases based on the operational framework for assessing the ethics of screening (Fig. 1).

3.2. Research questions

1. What is the current policy framework on preventive public health interventions?
2. What are the experiences as well as concerns of health workers who implement screening of women for Cancer of the cervix and antenatal mothers for Syphilis in Kenya?
3. What are the perspectives and experiences of women clients who have undergone screening for either Cancer of the cervix or Syphilis?
4. What are the specific ethics issues that can be elicited from these experiences and their relevance to public health policy and practice?

3.3. Broad objective

The broad objectives of this study were twofold: (i) to review the procedural, ethical-legal and medical considerations for mounting screening populations for disease and; (ii) to elicit both the provider and client perspectives of screening for Cancer of the cervix and Syphilis as well as ethics issues and concerns emanating from these perceptions.

3.4. Specific objectives

1. To review the frameworks for mounting screening services as an essential preventive public health strategy in Kenya;
2. To elicit the experiences; ethical concerns and challenges practitioners confront routinely during screening process;
3. To elicit the ethical issues connected to perceptions, motivations and expectancies of participants during screening for Syphilis and Cancer of the cervix;

4. To discuss the ethical implications of the clients’ perceptions to mounting screening for Syphilis and cancer of the cervix in Kenya.

Fig.1: A Framework for Assessing Ethics Issues in Screening Population for Disease (Adapted from Aday A. et al. (1993) 64
CHAPTER 4

Materials and methods

This chapter provides information on the study design, what procedures were utilized during the research – both for data gathering process and analysis procedures- and regulatory approvals.

4.1. Study design, recruitment and setting

This study was aimed at eliciting experiences and latent ethics issues related to screening from the client and provider perspectives as well as the public reproductive health policy environment. We gathered information from women attending Cancer of the cervix clinics as well as antenatal clinics (where screening for Syphilis is routinely done). This was a more feasible way of recruiting sufficient eligible clients for interview, albeit this may represent a self selected group. Only those who were able to independently provide informed consent were included, hence the restriction to the legal adult age (age of the majority in Kenya). Also, we interviewed the respective service providers and departmental supervisors about their perspectives and experiences with screening. Relevant national documents plus related publications were also reviewed (Appendix 1). We then derived conceptual categories related to ethics of screening populations for disease from the data. It was conducted entirely as part of an academic requirement in bioethics training. The outcomes of this study however, are relevant for policy and practice decisions.

The methodology for this study was entirely qualitative. It was based on questionnaires for policy makers/supervisors, service providers and focus groups involving women who were recruited from Nyanza Provincial Hospital; Kisumu District Hospital and Lumumba Health Center, all situated within the city of Kisumu. These sites were purposively chosen because they are the only main centers where screening for the target diseases is provided routinely. At Lumumba Health Center, 6 Focus Group Discussions (each with between 6 and 7 members) with
antenatal mothers undergoing screening for Syphilis were conducted; they don’t perform screening for Cancer of the cervix. Focus group discussions for clients undergoing Screening for Cancer of the cervix were done at both the Provincial Hospital (1 FGD of 5 members – based on the clinic schedules) and at Kisumu District Hospital (1 FGD of 6 members, while the other four FGDs had between 3 and 4 participants per group). The average numbers for each of these groups were low because of the low turn out of clients besides the difficulties of scheduling them. Sixty four women participated in these focus group interviews and five members of staff (Nurses and Clinical Officers) consented to fill in the questionnaires (Appendices 2–7).

4.2. Data collection procedures

Four experienced research assistants were recruited and trained on the study protocol. They enrolled the participants sequentially from the respective clinics over a three week period. Two each were assigned to conduct focus groups with the clients from antenatal clinics at the health center and the Cancer of cervix clinics at both the Provincial and District hospitals. In each case they also distributed pre-piloted self administered questionnaires to the health administrators and service providers under the ministry of public health and sanitation, particularly those who directly oversee or administer screening services. Only administrators and clinic staff (Nurses and Clinical Officers) who are involved with the actual screening process were included to elicit their perceptions, concerns and experiences with screening for the target diseases (Appendix 6). Additionally, specific national documents (Appendix 1) available were manually reviewed by the author and relevant information abstracted mainly to provide data on the policy and implementation environment.

Clients were referred for enrolment by the regular clinical staff in these clinics. The service providers had been adequately briefed about the study and referral procedure. They informed their clients about the study and those who expressed interest and willingness to participate in a
discussion group were referred to the research assistants for consenting. A room had been allocated specifically for this exercise. We anticipated inviting women consecutively during early morning hours when clients normally report to the clinics, until five to eight agreed to participate in each group. We expected this would ensure adequate representation from several potential strata. However, when only few clients were available specifically from the cervical cancer clinics, we resorted to forming a minimum of three members in each group. This was due to difficulties in getting these clients together in three of the possible health facilities where screening of cancer of the cervix is performed.

We enrolled participants sequentially up to the point when no new or relevant data seemed to emerge from further interviews. Each session lasted about 45–60 minutes. We made audio-recordings of each session after a brief orientation on the topic of discussion to facilitate transcription of the information; also we took observer notes (which captured in summary important relevant issues, such as emotional contents, personality demeanor and overall feelings of the focus group). Audio recordings were transcribed and translated into English by the moderator for each group and reviewed by the author based on the original audio-recordings.

Kiswahili language was used as the primary language of communication, since in most cases participants were mixed. All focus groups were conducted within the facility on the same day participants were recruited. This was more convenient since the participants would not have to return to the facility. Snacks were served during each session. No other compensation was provided.

4.3. Data capture instruments

The focus group interview guide (Appendices 2–8) had been adapted and validated from the ‘Alliance for Cervical Cancer Prevention (ACCP)’<sup>22</sup>. It contains standard questions for evaluating cervical cancer screening in the developing world. The study questions aimed to elicit among other
issues the participants’ knowledge of the target disease, concerns about developing the disease, perceptions of their own personal risk of Cancer of the cervix or Syphilis and acceptable options for preventions respectively, their motivations to attend screening clinics, disease expectancies (specifically as related to their beliefs about the source and consequences of the disease), communicating risk and test results to other family members; perceptions, feelings, concerns as well as experiences during the process of screening either for Syphilis or Cancer of the cervix, issues about repeat tests, privacy, confidentiality and access to services. Focus group discussions were tape recorded and supplemented with back up notes. Data on provider perspectives and experiences were elicited through self administered questionnaires given to the specific providers in the respective clinics and their unit or departmental supervisors. Desk review of national documents and publications (Appendix 1) was done to explore relevant information on policy decisions and implementation framework.

4.4. Ethical considerations

Approval for this study had been granted by the various administrative and ethics bodies from University of KwaZulu-Natal (Appendices 8 and 9), Kenya’s National Council for Science and Technology (NCST) (Appendices 10 and 11), Ministries of Health, Provincial administration, health department at the Kisumu City council, Kisumu District and Nyanza Provincial Hospitals (Photocopy of appendix 4 was accepted and endorsed by relevant authorizing officers and filed).

Each participant willing to participate was individually taken through the consent form – either in English or Kiswahili language as was appropriate (Appendix 7) by the research assistants and then enrolled to a group. Written informed consent (Appendix 7) was obtained from each participant and unique identifiers assigned to them. Only women who had attained age 18 years old (the legal age of independent consent in Kenya) and above (confirmed from clinic records by the referring service provider) were invited to participate, but there was no upper age restriction.
Some of the participants were initially hesitant to have their voices recorded, but agreed to it after a careful explanation of the purpose and the option to withdraw from the study at any stage if they so wished without any prejudice. Other participants were just concerned about discussing their personal issues with strangers. However, setting ground rules for the sessions, particularly to ensure confidentiality and conducting the sessions in a secluded place helped to reduce this anxiety. Also, all the four research assistants were females. They were also assured that they will be promptly attended to after the focus group session in case they were not yet through with any procedure such as getting back results, so that they don’t feel like they have wasted time or will be more disadvantaged because of their participation. This was ensured by the research assistants who alerted the service provider once the sessions were over.

4.5. Analysis

Two of the more experienced female research assistants who moderated the discussions (they had participated in similar capacities in other social research) transcribed and translated the audio-recordings of the focus group discussions. During the translation, we tried to keep the phrases and words as in the spoken language, to capture the context to the extent that is closer to the original language; albeit, we acknowledge that some information and features carried by the local language might be lost when such verbal expressions are translated into English. The author read through the entire data set to confirm accuracy and content validity.

Thematic content analysis of the data set was performed. Data were explored and interrogated manually using open codes. Participant experiences and views were extracted from the text, condensed by abstraction of both overt and latent emphases as well as unique experiences and expressions; these were then sorted out by relevant content areas. The resulting themes were developed into conceptual categories, which formed the basis of analysis.66. These were fitted broadly on the given theoretical framework of the study to reflect both the manifest as well as
unique latent ethics issues of mounting screening for both Syphilis and Cancer of the cervix at the level of its structure, process of implementation and intermediate outcomes. Further attempts were made to corroborate and triangulate conceptual categories with information from desk reviews including previous literature on policy decisions and ethics of mounting population-based screening.
CHAPTER 5

Results

The findings are presented along the broad conceptual categories which represents the client perspectives as they emerged from the interviews. Also, the latent ethics issues based on existing constructs are offered and later discussed.

5.1. Historical background, regulation and policy environment for screening

The policy guidelines on implementing control programs for cancer of the cervix and syphilis are more succinctly found in the National Reproductive Health Strategy, though related information on action components are scattered, in several documents for training or in training manuals for Sexual Reproductive Health (SRH) service provision in Kenya. Also, some of the relevant information is only found in the international policy and service provision documents on reproductive and sexual health. There are no specific national guidelines on how to mount screening for syphilis, but it is indicated in these guidelines that it shall be provided as part of a screening package offered to all antenatal mothers presenting at the clinic. Nonetheless, the national guidelines stipulate that before the procedure is carried out, “adequate reproductive health history should be taken and recorded and informed consent acknowledged. After the procedure the results shall be discussed with the client and she may be asked to return any time for advice, re-screening or care”55. Also, it is recommended that maternal screening for Syphilis should be done early in the first trimester to reduce child/maternal mortality and morbidity. However, given that a majority of women initiate antenatal clinic visits late (mean gestation of 5.9 months) and only some of these ever obtain blood tests (Table 1) few of them are likely to benefit from Syphilis serology tests. The strategic framework to operationalize these public health initiatives, lack details on how supportive services are linked or sustained.
From the Public Health Act of 1986 (Cap 242), it is indicated that Syphilis is a notifiable
disease and there is a compulsory requirement for its diagnosis and treatment as a sexually
transmitted disease to curtail transmission. In a case where the condition is deemed to be prevalent,
the medical officer of health may order for medical examination of the inhabitants of such
localities and failure to submit to such examination and/or treatment is an offence (Chapters 45 sec
a – c and 48, 51). Under these circumstances, screening for maternal Syphilis may be deemed
compulsory. The medical practitioner is obligated to notify client or her partner(s) about the
occurrence of the disease. But they are also required to educate, counsel and provide written
instructions about the condition to the clients and ensure strict privacy and confidentiality of their
medical records. Similarly, the clients or parents/guardians of children are to submit themselves or
the children to treatment and follow up until cured of the infection. Intentional conveyance of the
disease under this act is an offence $^{55, 64}$.

**Table 1: Profile of the antenatal care in Kenya**

<table>
<thead>
<tr>
<th>Key Issue</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antenatal care coverage for women</td>
<td>88% receive care from medically trained care providers, mainly by nurses; 2% receive care from Traditional birth attendants 10% do not receive any antenatal care;</td>
</tr>
<tr>
<td>Sources of care</td>
<td>Public health facilities – level 3 and 4 (71%)</td>
</tr>
<tr>
<td>Number and Timing of antenatal care</td>
<td>At least four visits recommended, initiated during the first trimester 52% make four or more visits 11% obtains care within first trimester and less than 50% by sixth month of pregnancy</td>
</tr>
<tr>
<td>Components of antenatal care</td>
<td>36% informed about pregnancy related complications by care givers More educated urban residents are more likely to have sufficient information About half had their urine and blood samples taken 13% were given information or counseled about HIV during antenatal care visits and 39% counseled on breastfeeding</td>
</tr>
</tbody>
</table>

*Source: (Central Bureau of Statistics (CBS), *Kenya Demographic Health Survey 2003*.Pg 123 – 128)$^{67}$
5.2. Experiences and concerns of service providers

Only three of the service providers filled and returned their questionnaires and one supervising staff did not (it was deemed she declined participation, after one reminder) while another proceeded on annual leave before handing over the questionnaire). Their responses are summarized in Table 2 below (this included the responses from their unit level supervisors. No substantive officer at the national policy making level was interviewed. No substantive senior officer was available and the alternative staff did not return the responses despite reminders. Transitions in the ministry of health after restructuring the Ministry of Health into both Medical and Public health services complicated the scenario at the headquarters).

Table 2: Provider responses on screening in Kisumu

<table>
<thead>
<tr>
<th>The issues</th>
<th>Their views and experiences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening as part of the health sector plan</td>
<td>It is a part of providing comprehensive health care;</td>
</tr>
<tr>
<td></td>
<td>It is not certain if there is comprehensive national plan for screening for Syphilis or Cancer of the cervix;</td>
</tr>
<tr>
<td></td>
<td>Not aware if a central coordinating body exist at the national or provincial health care levels;</td>
</tr>
<tr>
<td></td>
<td>Not certain of considerations for policy decisions</td>
</tr>
<tr>
<td>Their view of screening for Syphilis and Cancer of the cervix</td>
<td>Syphilis and Cancer of the cervix are rare but serious illnesses;</td>
</tr>
<tr>
<td></td>
<td>Effective screen tests, diagnosis and treatment for the conditions exist;</td>
</tr>
<tr>
<td></td>
<td>The target population for screening is distinct;</td>
</tr>
<tr>
<td></td>
<td>The screen tests available are widely acceptable;</td>
</tr>
<tr>
<td></td>
<td>Women do not access screening services for Cancer of cervix;</td>
</tr>
<tr>
<td></td>
<td>Services are accessible to those who are willing to undergo the test;</td>
</tr>
<tr>
<td></td>
<td>Screening has improved uptake for treatment of related disorders;</td>
</tr>
<tr>
<td></td>
<td>Majority of those who test positive do not come for follow up;</td>
</tr>
<tr>
<td></td>
<td>Contact tracing for partners of clients who have positive results for Syphilis is in place (Comment: usually done through snowballing);</td>
</tr>
<tr>
<td>Follow up of clients post-screening</td>
<td>Access to screening services for Cancer of cervix is inadequate;</td>
</tr>
<tr>
<td></td>
<td>Majority of those who test positive do not utilize follow up options;</td>
</tr>
<tr>
<td></td>
<td>A system for contact tracing is necessary;</td>
</tr>
<tr>
<td>Concerns</td>
<td>Lack of regular quality control checks;</td>
</tr>
<tr>
<td></td>
<td>Inadequate space to guarantee sufficient privacy of clients;</td>
</tr>
</tbody>
</table>
User fee is usually charged as part of cost sharing, but this is highly subsidized to make it affordable. The rates vary with the level of health care, being higher at the district and provincial, these being referral care facilities. The specialized investigations are however still unaffordable for a greater majority. They also indicated all the screening services are integrated within the basic / routine outpatient care package. Screening for Syphilis is routinely provided nationally in all antenatal and patient support centers whereas for Cancer of the cervix, screening is on opt-in basis and is available in a few of the health centers, but test kits are often unavailable.

5.3. Perceptions and experiences of women who had been screened for Syphilis

5.3.1. Client knowledge and awareness about Syphilis

Most clients appeared to have a satisfactory level of awareness about the source of the disease and some of the diverse adverse consequences of Syphilis – to the mother, such as death or barrenness, strained relationship between spouses and pregnancy outcomes such as loss of fetus. The majority expressed knowledge that the disease can be easily transmitted, but they varied in opinion on how this occurs. Most of them indicated that:

‘It is a sexually transmitted infection which is painful’.

A few women expressed different opinions about the source of disease, indicating that:

‘It is transmitted by sharing pants with an infected person or passing urine in the same place where an infected person had urinated’;

‘If it overstays in your body, it can lead to AIDS’

‘I don’t know about it, but I have heard about it’.

During discussions, it emerged that the women associated Syphilis with severe adverse events. They perceived the disease as sufficiently serious and stressful to warrant their attention, both at personal level and including their close relations, as revealed by the following sentiments:
‘In pregnant women, it can lead to miscarriage and blindness to the fetus’;

‘It is a dangerous disease, if you contract it you cannot get pregnant’;

‘It affects the womb. ... so it should be detected early and treated’.

‘If a close relation has this disease, I will feel bad because it is not good in life ... i will advice her to go to the doctor quickly before the disease worsens to a condition she cannot walk...it can kill her so she should go to the doctor quickly!’

Some of them also perceived the disease to be treatable if detected early, either at the hospital, or according to one of the women, you can use herbs if the hospital approach failed:

‘You can go to the hospital to be screened then start on medication if found to be positive’

... if it doesn’t work, use herbs’.

They were also aware that it can be latent in the body; therefore, and one should know her status by going go to the hospital/clinic for medical check up and treatment, as revealed by the following statements:

‘Before it is detected, you may not realize you have it; but if you are aware, you can go to the hospital and be treated’;

‘You can come to the hospital when pregnant or sick to be treated for it so it does not spread to the whole body’

Additionally, because of the potential for psychological and social stress, and being a sensitive disease condition, the participants indicated that it is necessary for those who test positive and require treatment to be provided with both social and psycho-emotional support. However, this should be done skillfully and with understanding without being judgmental, as revealed by the following statement:
‘If results are positive, you should be given guidance and counseling politely and not harshly or by throwing words’

Table 3 below summarizes the participants’ perspectives of the screening and Syphilis. The key issues arising were that there is a societal sense for individuals to take personal and moral responsibility to protect themselves as well as the larger community and to use effective means to treat the disease whether through traditional or contemporary medical approaches. This indicates they were cognizant of the critical need for effective prevention and treatment of the disease.

Table 3: Participants’ perspectives about screening for Syphilis

<table>
<thead>
<tr>
<th>Perspective</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening is an important procedure for pregnant women. It helps them to know their status by detecting the disease early.</td>
<td></td>
</tr>
<tr>
<td>You can get effective treatment at the hospital</td>
<td></td>
</tr>
<tr>
<td>The disease is preventable by ‘taking control of one’s behavior and creating awareness among the community members’</td>
<td></td>
</tr>
<tr>
<td>The individuals must take personal responsibility to protect themselves as well as the whole society in the following ways:</td>
<td></td>
</tr>
<tr>
<td>◦ ‘observe good behavior’</td>
<td></td>
</tr>
<tr>
<td>◦ ‘… take care to protect yourself after screening’</td>
<td></td>
</tr>
<tr>
<td>◦ ‘use condoms during sex to prevent the disease’</td>
<td></td>
</tr>
<tr>
<td>◦ go to the hospital to be screened then start on medication if found to be positive’</td>
<td></td>
</tr>
<tr>
<td>If you have a genital wound go to hospital for screening</td>
<td></td>
</tr>
<tr>
<td>‘Only you as an individual gains, others will not be concerned’</td>
<td></td>
</tr>
</tbody>
</table>

5.3.2. Perspectives about being informed of the disease

Some of the participants indicated that the health staff at the clinic informed them about Syphilis and a range of tests to be done on them. Others also stated that their understanding about the disease had improved after undergoing the screening procedure, as revealed by the following statements:
‘I have a better understanding because they test your status and teach you about caring [of] private parts’;

Others however, expressed different opinions:

‘They didn’t discuss it with us; they just checked the status, so we are blank’;

‘I did not understand it well since the child was disturbing me, and I kept going out’.

The following statements reveal the participants’ perceived advantages of screening for Syphilis (the thematic constructs are bolded):

‘I know the disease exists and screening helps me in making [a] decision before engaging in sex with a man’;

‘It is important to know the status of your partner in case you get pregnant so that you don’t suffer’;

‘Knowing your status early to plan your life as a couple before you start your relationship’;

‘It alerts on your condition, then plan; avoid or take precautions not to contaminate yourself or spread it to others’;

‘It helps people go for treatment especially when the other people who are reluctant to go will go after they know they are not alone in this’;

‘I don’t know what to say about that’.

5.3.3. Key ethical concerns

The specific concerns expressed by the participants were varied across the groups and for different points of the process.
Information giving: The language used and mode of presentation during pretest counseling and education influences the emotional outcomes, understanding of the procedure and attitudes of the clients towards the exercise. Most clients were comfortable with the language since the care providers used what language they would understand well, yet some still missed out because the nurse was talking too fast.

Some felt that they did not have time to discuss the information provided to them about the disease and the tests intended, even though they did not understand some of the issues, as revealed by the statement that,

‘... There is little room for interaction and some talk too fast and clients too many to allow time for discussions ... so they want you to give other people room’.

Psycho-emotional stress: There was a sense of fear or anxiety about the outcome of the tests. Some explained that those who test positive become anxious and are worried to the extent that some may commit suicide. Such extreme stress is especially possible if they are not counseled well before or if they are not told about the test for Syphilis early enough. They indicated that pretest counseling and client education are essential to minimize potential severe emotional adverse consequences related to the test among clients. Additionally, being sufficiently informed in time would be helpful, as one indicated that,

‘We were not aware of it; it is better if they inform us early so that we can involve our partners instead of being tested alone and my partner is not there’.

‘If am tested and am not counseled, may be I can even refuse because it will make me think that these people are assuming I have Syphilis and if am counseled, I can just agree to be tested’.

Informed consent: Seeking informed consent first or notifying the clients about the tests before they are administered is essential, especially because of the complexities of decision
making. This clinical area should also guarantee privacy of clients to assure their confidence. The participants had varied opinions and feelings about undergoing screening during antenatal visits. Some felt they had an option not to be tested, while others felt otherwise, and some were ambivalent. But there was consensus that taking the client through consenting process accords them an opportunity to clarify their positions before the procedures, in case one had a divided mind, such as this one who said that:

‘I have two minds. One it is good since the disease is treatable. Two, I feel stressed, because I will be asking myself – where did I get it from’.

The experiences or perceptions of tests seemed to elicit various emotional expressions from the participants including, acceptance and appreciation, expectation of treatment, worries, fatalism, dejection, sense of relief and agitation. One of the participants indicated that:

‘If you are tested and not counseled, you can be shocked’;

‘I had thought about it ... I knew if I had it then I was HIV positive’.

Some participants felt that since they were not prepared initially before coming to the clinic and only obeyed what they were told to do. They might not have understood the issues of screening. A few indicated that they were threatened and others were concerned with the harsh or judgmental attitudes of the doctor’s, for example, that:

‘A fine will be imposed if they don’t concentrate and later seek for more consultations’.

**Waiting time/time burden:** Most of the participants felt the waiting time before the results were released to them was too long, sometimes running to a whole day.

**Pain and discomfort during the procedure:** Another key concern was potential for pain during finger pricking or during the pelvic examination. Some participants indicated that undressing before a male care provider, for example, during pelvic exam to confirm genital
lesions, can be embarrassing to them, particularly when they are not feeling sick. Talking about sexual experiences and relations may be uncomfortable too, in that context.

**Disclosure of results:** A majority appreciated the fact that results are given to each individual at a time and in private.

‘I was happy and satisfied because we talked the two of us and no one knew what we had talked about’.

They were also content with the level of confidentiality accorded. But they were uneasy with the potential for the results to be mixed up, for example in case there was a problem with labeling the samples, hence their caution that:

‘they should not rush and give wrong results’.

The name tagging or labeling of specimen bottles is more assuring to the clients that the results are the correct ones.

**Opt-In / Opt-out: is there a choice?** While some of the clients came purposely for screening, others felt they didn’t have a choice since it is compulsory as indicated by these statements:

‘Yes, I came purposely for the test to know my health status’;

‘I have been going purposely to be checked my status, I was not pushed’;

‘All first timers attending the antenatal clinic, must be screened for all the diseases’;

‘I always heard about it, but not yet tested, till I came to the clinic and the doctor requested for it’;

‘It is a disease that must be screened for during pregnancy, so if you are free you just come, you don’t wait to be told’;

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‘We were told it is a rule to undergo the test ... even if you did not come for the screening’;

‘I had made a decision to be tested before I got pregnant, but at the clinic I was told it is a must’.

5.3.4. Expectations and preferences

**Required support:** One of their expectations after the test procedures was psychological support, but this should be done ‘with respect, dignity and politely’. There was a sense that the participants were sensitive to the attitude and sex of the care provider. They preferred a friendlier demeanor; a few more particularly preferred female staff attending to them. For example:

‘If results are positive, you should be given guidance and counseling politely and not harshly or by throwing words’;

‘It depends on how you find the doctor, how she/he talks to you’;

‘At first I felt embarrassed when the [male] doctor told me to undress and climb up the couch [to be done vaginal exam]; but the doctor talked well and urged me to be open so as to be helped’.

**Disclosure of information to relatives:** However there is general reluctance to divulge information on their test status to people close to them, except in some cases, if the client has a spouse they can trust. This may have a bearing on the psychosocial support they might need.

‘Its better if its I who breaks the news to my husband and not anyone else, because in the hospital we are told the results are confidential’;

*If it’s your husband, it’s okay ... because you will be able to plan your life and know how to stay, because you stay together and it’s important that he knows*.

**Handling of Results:** Results should be given ‘secretly’ (in private and in confidence). The information given is verbal, but the results are written in a book which the clients carry home.
Generally they were satisfied with the way the results are handled from the laboratory to the time they are called in to receive them and the information given after the test:

‘I am satisfied with the information given after the results because they know your results when they take your specimen, they label them, hence you are sure the results you get are yours’.

Follow up: There were varied perceptions about coming for or undergoing repeat examinations. While some appreciated that it may be necessary, others felt suspicious of the intentions of the repeat test while some were unhappy with it or felt anxious and worried at the request about it. Also, others felt they would dread it because of the long waiting time. On the other hand, some felt that they would just come because they have been asked to do so.

‘I can just go back if required because I don’t know why and just in case I have the disease but it was not detected at initial screening, so its good to know what is happening’;

‘I can just go but asking myself “but I had already undergone the test; why are they telling me to repeat it?” May be I got it from somewhere!’;

‘I can’t be happy because the initial results were bad. So I can’t be sure of my life’;

‘It would be difficult if [I] am going to spend the same time waiting for results’;

‘I cannot come back ... I don’t know doing what’.

5.3.5. Barriers and enablers of screening test for Syphilis

From the discussions with the participants, we elicited what the clients perceived as possible barriers to accessing screening tests at the initial or repeat tests. Some of the factors include fear or anxiety about the potential to test positive (fear of outcomes) and some stay in denial; some women ‘go to the traditional midwives so they don’t know their status’ (alternative care where screening is not mandatory). However, some have resigned to their fate while others fear their
spouse and/or their reactions should they go for the tests, as one indicated that ‘some are not allowed by their husbands because of the way they “move” (moral behavior)’. Also, lack of money (cost factor); being asked to return after initial test; long waiting time (time burden); long and complicated process; long walking distance; fear that another person may know their status; worries about initial test results. But some ‘do not believe you can have the disease’ while others fear that the ‘staff attending to me is familiar but I would not want my status revealed’, thus the potential to be stigmatized. Some may simply ignore, since the test may not be a priority to them.

On the other hand, some of the perceived motivators to utilizing the services or what would make it easier for them to use screening tests included focusing on the Syphilis test alone at a time, rather than a battery of tests at the same time. This may reduce the waiting time and accord time for interactive discussions and dialogue. Also, negative test results; use of private health facilities; having the right test facilities in one place; counseling; mobile services; doing it on weekends to cater for people who are busy during the week; door-to-door testing; creating awareness and advocacy were important motivators. The majority appeared to know where else they could access the screening services.

5.4. Client perspectives and experiences with screening for Cancer of the cervix

5.4.1. Client knowledge and awareness of the nature of the disease

Most clients were aware of the symptoms and consequences of the disease as well as site affected. Some revealed that they only understood more about the disease after going through the health education sessions conducted before the screening. They said that it is a cancer that:

‘It affects the inner part you can’t know, except the doctor who tests it know what it is’.

They were aware that it occurs in the genital tract of women and can be treated if detected early, but this is not easy when it is discovered late. One client associated its source to be ‘too much sex’.
Others associated it with genetic inheritance, poor genital hygiene, smoking cigarettes and abortion.

Some considered it a greatly ‘disturbing’ disease that also ‘hurts’, especially because of its ‘menstruation-like’ symptoms when it occurs in old age. This may mean that some women in their postmenopausal period feel really confused and disturbed emotionally or are just more conscious about menstruation-like events when they occur, as seen in this case:

‘you experience abdominal pains, blood and water comes out; like me an old lady like me I had stopped giving birth long time ago, I stopped menstruating many years back, so that it was is disturbing me like the way they’ve screened it, what will they do?’

Because of this they indicated that there is need for them to learn more about the disease, seek prompt medical intervention and spiritual as well as emotional support when you have it. They felt that attending screening clinic enabled them to learn more about the disease. The uniqueness of individual needs and experiences versus group needs could be an issue to be considered during client education. The following statements show some of their sentiments:

‘When you come to the hospital you will be able to know the disease you are suffering from. Like me, I knew there will be blood discharge, but did not know much if it was a disease. Going to the hospital is good, it made me know the disease exists’;

‘… like I had not come for the screening and I didn’t know the disease could be detected, so it is advisable to go for screening even before seeing the signs’;

‘Me I think that I have better understanding than before, because I used to know that cancer is caused by cigarettes, I learnt that the disease is not caused by cigarettes alone it can be inherited from family background and also if you see that its in your family lineage its better you go for screening in time so as to know if you don’t have it or if you have it know how you can be helped in time’.

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Respondent 2: ‘I don’t know much, I found when they had already taught about it’.

Moderator: ‘just tell me the little you know about the disease’.

Respondent 2: ‘it sucks blood and it causes wound to the affected area’.

5.4.2. Disclosure of known status to relatives

Letting the close relations to know about test results was generally considered positively in view of the potential support they would receive from them, but this may vary depending on the bestowed or positional responsibilities in the family. However there was strong preference for the client herself to divulge the information, as one commented that:

‘I will prefer to be the one to tell them since I know how they are. Some may be shocked and distressed’.

5.4.3. Access and use of screening services

Some of the clients had come for other services unaware that cervical cancer screening services were available, but were then referred to the clinic for screening of Cancer of the cervix. On the other hand, some came on their own initiative after they saw advertisements on information posters, while others were coming for repeat testing. Some felt they were ‘pushed’ by the doctor to take the test.

5.4.4. Concerns and ethical issues

In terms of their perceived experiences with screening for Cancer of the cervix, we elicited the following as some of their perceived concerns:

Bodily and emotional stress:

‘Some people come when they already have disturbing symptoms of the condition’

‘You should just be strong and have hope’;
‘All I want is to be treated and get well … because if am still sick, they won’t believe …’

Clients coming with already existing symptoms may have mixed or split feelings. Also, they may harbor contradicting expectations which complicates service and care needs of the clients.

**Enquiries or probing into client profile:** Some felt they are being asked about issues they consider difficult (or probably irrelevant) during history taking as one client said:

‘I was asked about the last time I gave birth, but I had forgotten since it was a long time ago’.

**Post test care and coping process:** Positive test results presented the greatest challenge to handle, given that cancer inherently induces fear, anxiety and loss of hope both to self and the family. Being aware that a positive test may as well mean one already has an advanced disease, for example, one of the clients remarked that:

‘If you know your status, you won’t live long. The shock will kill you. So you are better off not knowing’.

The participants were concerned about what would be done if the test result turns positive for the disease as well as what help would be provided given the potential for stress after the test. This may be further complicated by the inadequate system for care and support for chronic illnesses. However, some were more optimistic:

‘Mmh, now, if they get us with the disease its good because now I can be given medication, like now I have been told to come on Tuesday to the clinic’.

**Effectiveness of the test:** Their concern was about the possibility of missing the disease while it is already ongoing but not yet overt [false negative test results in latent disease]. On the other hand, some women come with existing symptoms which might be due to other conditions,
which might complicate the picture and disclosure of the test results. In one incidence, a client reported this:

‘When the nurse told me to lie down to be screened, she said that my case is hard and I had to wait for the other doctor whom she called to check on me. I believe in God; so according to His will so be it, am waiting for the other doctor.’

Also, a negative test result might be considered as a false one if a patient with overt symptoms is fixated on getting an answer at any rate or possibly living in denial, as expressed in this statement:

‘... before getting inside you are told everything, so when you come out of that place its you to accept or deny, but me what I see its good, you accept the result, come to terms with the situation and leave things to God and life will not be difficult, but if you live in denial you will shorten your life span and starts to regret that I wish I knew, I would not have gone for this test, and being told about this disease’.

Privacy, disclosure of information and test results: Majority preferred the sessions to be strictly private. A few of the participants felt that there is potential for breach of confidentiality, for example if other people knew about their test results, hence this should be guarded by the attending clinician. Some clients come with fixed mindset, and may find it difficult to concentrate on the information provided about the disease and the tests. Hence, balancing autonomy and paternalism may be made more complex, for example, some women felt that they were coerced to take the test.

Various participants felt that the information they were given was sufficient, while others indicated that they were simply asked questions, but not given any information. Also, a number of them claimed they had already made up their minds, irrespective of the information context at the clinic. There was prolonged waiting time for the results after the initial pelvic examination, sometimes coming after days and this only heightens anxiety. Delay to release results tends to
heighten anxiety for clients. Most of the participants felt that this should be expedited, as summarized in this statement:

‘you should be told about your results immediately instead of waiting, since after the test, when not told you don’t know the results and your heart is not settled’.

The result should be given in a language that is easy to understand. Some do not know how to read, or if written results are not verbally reinforced is considered impersonal.

**Follow up and repeat tests for surveillance:** Some participants felt that tests should be done until the disease ‘you are suffering from’ is known, the reason being that a repeat test may reveal it, for some this would be unacceptable, as indicated by the statement that:

‘I will not accept because she tested me the first time. Is it that she didn’t get it? I am not at ease since it’s already tested …’

Issues related to fear of the disease, ignorance, time burden, cost of travel and staff were elicited as potential factors that may de-motivate clients from complying with follow up schedules.

**Pain and discomfort:** During the pelvic exam, some clients may feel discomfort and pain, which can make some clients to fear undergoing the test. Some of the clients preferred female staff to perform the pelvic examination on them. This was particularly among those who had no symptoms because they felt a bit embarrassed undressing more so before a ‘stranger’ who is male, but were reassured by the presence of a female assistant.

**Client satisfaction, confidence and trust:** Participant or client confidence and trust have an important impact on the client-clinician relationship, privacy, decision-making/consent for screening as well as the clients’ response to the voluntariness or compulsoriness of the screening exercise. Some participants were happy with the services at the screening clinic, including the provider approach and sufficiency of information given after the test results. Some of those who
obtained negative test results felt that they were not given further information about the disease and what to do next (possibly feeling ignored). A few of the participants felt that the sessions were interactive and were satisfied with the approach. However, for some the sessions were very short and they seemingly were caught unawares or were expecting more interactions. Hence they expressed the need for ‘thorough explanations’ or a level of explanation that would accord them clear understanding of the relevant facts to enhance decision making about the screening process during subsequent visits.

Mental stress during the wait for results and poor coping mechanism were also important issues of concern.

5.4.5. Public awareness and access to service

There was concern that there is little community awareness of the condition as well as poor availability of drugs and counseling/psychosocial support to those who test positive (this may be a potential cause for withdrawal from follow up among those who test positive, but it may also send a wrong signal to others that it may be of no use because nothing shall be done). Equity in distribution of community resources is essential in building strong health delivery systems.

It is imperative that those who submit themselves to the tests should access post test services, such as psycho-emotional support, medical as well as other supportive or definitive therapies as may be indicated. This becomes more relevant also to meet the needs of clients coming for repeat examination or other related service. Lack of public awareness may also adversely affect availability, access and uptake of services by the targeted groups. Additionally, it may counteract the commitment to pursue reproductive health goals by the community as a collective agent. When the community is sufficiently informed and meaningful engaged in the health policy decisions it is more likely that health outcomes and other benefits will improve, particularly where their interests are likely to be at variance with that of the state, as may occur in screening for Syphilis.
In terms of possible hindrances to utilizing screening services, they felt that some were frightened about the disease and thus feared getting a positive test result; fear of the tests; lack of fare to the hospital clinic; the kind of staff available; husbands may prevent their wives from attending clinic or reject her if she tests positive; fear of a breach in confidentiality; negative staff attitude; lack of someone, especially a family member, to accompany them to the clinic. Also, association of the disease with sexuality raises the issue of potential for stigma.

On the other hand, the disease condition either personally experienced or observed in others may stimulate one to come to the clinic for test. If a client is assured of privacy and confidentiality of test status; clean environment and where these services are easily accessible; having day offs to attend the clinics; sensitization of husbands/partners; assured good services at the clinic and attentive, willing staff would be good motivators of uptake of services, uptake improves.
CHAPTER 6

Discussion

This chapter discusses outcomes of the study according to the topical themes previously given.

6.1. Policy environment for program implementation

A review of the available national documents on reproductive health indicate that although screening for Syphilis and cancer of the cervix has been ongoing for along time in Kenya (before independence in 1963 – for Syphilis), there has been a major shift in reproductive health policy towards providing a rights-based, comprehensive and integrated services. The responses have been stimulated by the recommendations contained in the Action Plan of the International Conference on Population and Development (ICPD) in Cairo 1994. The sessional paper Number 1 of the year 2000 spells out the strategies and objectives in reproductive health and reproductive rights. Based on these, the relevant national strategic documents, training manuals and communication guidelines have been produced. The guidelines for service provision emphasize on skilled attendance, clients’ rights, acknowledging informed consent, recording client information, and confidentiality. It is acknowledged that an elaborate conceptual and policy framework exists for program formulation, but the relevant documents are not widely available to the service providers. If critical documents and guidelines are not easily accessible to users for referencing, then quality of service delivery may potentially be compromised for lack of compliance to guidelines.

Global shifts in policy directions, variations in testing and treatment approaches should be adapted to the local context based on local evidence and tailored to suit consumer needs as part of social justice and to ensure unmet local needs are addressed. Also, cultivating local participation in decision-making on how best to mount screening for Syphilis and Cancer of the cervix is critical,
yet it is still a major challenge for lack of adequate public awareness to allow substantive engagements.

Screening for Syphilis particularly targets antenatal mothers to improve their obstetric outcomes and assure quality of life for both the fetus/baby and the mother\textsuperscript{58}. Similarly, prevention of Cancer of the cervix is aimed at reducing morbidity risks among women of reproductive age. This is realized through health education, screening to detect conditions early and provide prompt effective treatment or referrals for supportive care services. The ‘right to health (care)’ approach adopted for the health service delivery (including screening) in Kenya\textsuperscript{60} appears to emphasize on providing a minimum package of services and resources redistributed to favor the more vulnerable or worse off groups (high risk approach) to improve their range of opportunities for well being. The decentralization of screening services through the different levels of service delivery\textsuperscript{60} as well as adopting support supervision at the district level health care and networking with the community is more likely to enhance provider involvement, community acceptance of services provided, access and service uptake by the target group, and in the long term, result in program cost effectiveness. However, infrequent undertaking for quality assurance of related procedures and staff performance may still compromise service outcomes and efficiencies.

6.2. Perceptions and experiences of women

6.2.1. Knowledge and awareness

From the current study women’s perspectives with regard to screening services for both Syphilis and Cancer of the cervix follow similar trends. However, their views of these services generally reflect a more complex mix of both traditional and contemporary socio-cultural mores and codes. Hence interpretations of their meanings and structures and definitions of needs can only be reliably understood within their local contexts. Also, there seems to be a dynamic interface between the medical health model and the traditional health models. The clients’ perspectives of
ways to achieve health/well being, which is their core concern, whether through medical or traditional (non-formal) health care approaches are undifferentiated. Such a dualism may also influence the way they perceive and interpret existing health intervention programs such as screening. The National Health Sector Strategic Plan II (2005)\textsuperscript{60} indicates that the health service delivery will follow a ‘rights-approach’ but does not clarify what this means. The regulations\textsuperscript{64} restrict adverse lifestyles and practices while promoting positive ones and interventions that would improve maternal and child health regardless of the cultural norms. The underlying ethical requirement then is to make the services universally acceptable and accessible with adequate decision options to facilitate reasonable choices. This approach is stipulated in the mission statement of the Ministries of Health\textsuperscript{60}.

6.2.2. Key ethical issues and concerns

Information giving and informed consent

The cultural norms, policy environment for service delivery, implementation criteria and choices available to clients would affect the way they construe and construct their roles, responsibilities, disease expectancies and health behavior responses. The likely ethical tension for implementing screening programs is the balance between respect for personal rights/choices and the intervention for the common good that may limit individual liberty. A difficult situation that may confront the health provider is how to respond to an ambivalent client or one who would (entirely) entrust the health staff to make screening decisions for her, despite candid information sharing. Some of the participants in this study trusted that a medically-trained staff would make the important medical decisions for them since by their training they would know what is best for them or is in their best interest (reasonable standards criteria). More often this position is reinforced by the power balance in favor of the service provider\textsuperscript{52} and the clients’ perception of risks and their fatalistic attitude (apparent helplessness) towards diseases seen as severe, painful,
disturbing or dangerous. This could raise the ethical concerns of coercion and paternalism on the part of the clinical staff on one hand and lack of voluntarism or significant autonomy for the procedures. Principally, the staff would rely on their moral and professional codes plus existing regulations to decide on the management strategies. Also, they may disclose adequate information, encourage relevant choices and protect privacy and confidentiality\textsuperscript{16}.

Clients’ knowledge and awareness levels of the sources and consequences of a disease influence their health behavior and responses of individuals in the community. For example, it may help in de-stigmatizing the condition in the community, or by the individuals themselves. Croyle and Lerman\textsuperscript{66} have observed in genetic counseling that clients’ decision to seek or accept the test procedures and whether they would recommend it to their close relations was informed by their perception of their own cancer risk, similar to our observation that perception of risk of Syphilis infection or Cancer of the cervix, knowledge of the disease and where to get help as well as their current and past medical experiences influenced their decision making and response.

In this study, it was apparent that the participants preferred a more interactive discussion during health education and counseling sessions. An interactive approach to health education, especially with communication aids, provides potential for peer support/decision support in risk comprehension among participants which can enhance their decision-making and responses or help with behavior change\textsuperscript{68, 69}. Their self efficacy in decision-making at and post screening depends on the validity and quality of information provided. This is particularly important since there are multiple tests carried out at the same time and the sessions are wholly verbal with no written information to take home. The potential for confusion or misunderstanding of the intentions of the screening tests is high.

In the current study, other factors that may confound clients’ decision making or responses during and after the screening procedures included how they perceived staff attitudes, competence
and level of interactions; the individual’s clinical state during screening; level of social support available; client’s attitude toward the disease level of awareness of the disease, comprehension of risk and screening procedures and self efficacy.

Some clients tended to conflate Syphilis and HIV tests; on the other hand, some thought that having a positive Syphilis test result was tantamount to being HIV sero-positive. This indicates that there exists some tendency for procedural and therapeutic misconceptions in this approach where multiple screening interventions are implemented at the same time. Additionally, it is possible that dealing with many conditions at the same time may cloud clients’ understanding of the disease conditions and the intentions for screening in each case. This has policy implications in terms of implementing different types of screening interventions but which target the same population group or similar risk groups in a population.

**Pain and Discomfort**

Screening is a beneficent response that simultaneously focuses on the well-being of both the individual and public. The key challenge is how to balance the intended benefits and harms inherent in the procedure. Taking appropriate procedural measures may be sufficient to minimize anxiety, discomfort and sense of embarrassment women may possibly feel before or during the procedure, particularly during pelvic examination in screening for Cancer of the cervix. Foreknowledge of the potential for extreme psychological stress after receiving post-test screening test results can adversely influence the client’s readiness for the screening procedure. Also, the level of information disclosed particularly about the procedure affects the perception of potential level of harm hence readiness to undertake the test at all.

Anxiety or extreme distress may distract a client from considering the most salient features of the situation in addition to narrowing their focus of options available. Also, the potential for some clients to feel pain, a measure of physical or emotional discomfort and fear of being stigmatized
requires a delicate balance between the needs and context of the clients versus the goals of the screening exercise as a disease prevention approach. The ethical requirement is to have adequate guidelines for pre- and post- screening counseling and, provide relevant training and regular updates for the staff involved. At the policy level, more stringent considerations are required in a screening context fraught with high potential for psychological (such as cancer of cervix) and / or social risks (as for Syphilis) to minimize infringement and harm to the individuals and/or their families that may emerge as a result of being identified as being at increased risk.

On the other hand opt-in screening contexts such as for Cancer of the cervix must consider levels of acceptance of the procedure versus the number needed to screen to prevent one case of the disease as this has an impact on its cost effectiveness as a decentralized service. Also, it should consider the contextual level of public health necessity for implementing this form of screening approach on a wider scale, for example, the level of prevalence and resource availability for care and management. Social acceptability of test procedures is a critical factor in the success of the screening process as it affects the number utilizing and benefiting from the procedure.

There is a potential conflict between the legal requirement to notify Syphilis sero-positive cases for purposes of disease surveillance and moral and public health constraint to trace and treat partners versus the concern for confidentiality and client autonomy. Some clients preferred that if at all, they are the ones to disclose their status to their partners or close family members and anyone else doing so would be breaching rules on confidentiality, apart from jeopardizing her social status and marital relations. This presents an ethical dilemma, when considering the provisions for contact tracing for purposes of treatment of Syphilis and potential consequences. Public release of unidentified surveillance data may incur social prejudice or economic loss yet on the other hand it is such populations that may benefit from allocation of more prevention and care resources from being identified as bearing a disproportionate burden of the disease.
Time burden and cost of screening

The time burden (as a hidden cost) constitutes the period that clients have to spend going through the entire process of screening, including disclosure of results. Prolonged waiting time may potentiate uncertainty or exacerbate clients’ existing anxieties especially when no adequate preparation or information is provided. Also, time could be experienced as problematic for clients, when limited or lacking, possibly reinforcing their perception of care as impersonal and insecure, and their need to seek alternatives. Prolonged travel and waiting time as well as costs charged are barriers to uptake of screening services. Some clients noted that they would particularly not come for a repeat / follow up examination if they would still experience the long waiting time. However, innovative and more acceptable approaches to reduce the waiting time may be sought. Issues of acceptability of a screening procedure may complicate its micro-availability (as a distributive concept) because it requires conformity to or cooperation with the social norms.

6.2.3. Expectations and preferences

From the clients’ perspective, their key concerns were respect for each client as an individual throughout and after the screening process, effective interactive dialogue before and after the procedure, ensuring their privacy and confidentiality of results, effective treatment of outcomes, and friendly environment at the facility, gender sensitivity and reduced time burden. Whether the screening procedure was an opt-out or opt-in one did not considerably matter to them, although some of them understood that they have a right to refuse the intervention. This indicates that the expectation of these participants is for the service to be provided as a health good, yet in the right conditions in which their human dignity can flourish. However, client perspectives of screening in this setting may be more complex and not typically follow conventional ethical categorizations, although varied ethical elements can be gleaned from the wide-ranging community perceptions.
CHAPTER 7

Conclusions, Recommendations and Implications of the study

This chapter highlights the critical issues elicited from the study, their applicability to the context of mounting screening in Kenya, particularly in Kisumu district as well as limitations. Recommendations for program implementation and future studies are also provided.

7.1. Conclusions

Significant challenges exist for both service providers/supervisors and clients in handling broader concepts and consequences of screening. Screening for Cancer of the cervix and Syphilis are practiced as part of the national reproductive health strategy. Strategic documents, including the national reproductive health policy and the national training and procedure manuals specify some of the guidelines to follow when implementing screening with the clients. However, these are not widely available to the providers for ease of reference. This may mean providers lack constant supervision or progressively reliable sources for reference. Regular quality assurance and quality control measures to ensure validity and compliance with health care guidelines are critical to ensure the intentions of screening are appropriately fulfilled. Also, tailoring the screening process to the individual’s need can help in improving client satisfaction as well as decision outcomes.

The overall uptake of screening is low while only few clients benefit from timely use of services. Participants had some general knowledge about either of the diseases and the benefits of screening to them or their relations, but they were also concerned about the potential limitations of screening as well as threats from disease. Some of their concerns including potential for psycho-emotional stress, social prejudice, impersonal or lack of interactive communication, reluctance to disclose to close relatives and distaste for notification and provider related barriers, reflect both the ethical and programmatic challenges related to screening for Cancer of the cervix and Syphilis in
the local context. This indicates that interpreting ethics issues related to screening requires a nuanced approach considering that individuals’ mundane experiences are uniquely intertwined with their traditional as well as contemporary lore. Their experiences revolve more around their personal or group experiences with staff or the procedures during screening, but which were not expressed to the service providers, perhaps for fear of retribution or inadequate communication. This means clients lose opportunities to open up. Coupled with current or previous adverse medical experiences, tension between voluntarism and paternalism in screening may be reinforced.

7.2. Implications for policy design, implementation and service provision

Ethics issues of screening population for disease such as resource allocation and distribution, consent process, supported decision making, information disclosure post-testing and psycho-emotional support are critical considerations for policy design and service implementation. There is a need to train service providers or supervisors of screening on how to deal with broader contextual reproductive health issues that are likely to affect the client perceptions, service uptake and compliance. Clients indicated their need for enhanced decision-making through appropriate communication, adequate information giving and decision support. This would call for apt staff training guides as well as job aids and support supervision. Ultimately they would provide environments that support dialogic communication and understanding of screening requirements, compliance, understanding risk and voluntary decision-making for screening. This could enhance uptake of screening procedures reproductive health services.

The policy design for reproductive health services and structure for implementation should engage more with the community (bottom-up approach) particularly where the disease prevalence as well as the potential for multifactorial causes are high as this will provide the critical local qualitative information to inform the service provision process, resource allocation and how to manage potential harms from screening diseases fraught with high personal and societal risks. The
potential for grievous social and psychological harm is high for both of these diseases. Also they are associated with high levels of morbidity and mortality which can be largely improved through public health responses. Hence, a more careful consideration of both the demand for public health intervention through screening vis-à-vis the overall outcomes as perceived by the risk / target groups should be guaranteed at all decision and implementation level. However, the context for public health intervention responses and attendant ethical issues may be more complex than hitherto perceived.

7.3. Areas for further research

There is a need to further evaluate factors that motivate or hinder uptake of screening services as well as structures available for psychosocial support and staff coping mechanism in a screening environment for high risk disease. Also, further research is necessary to evaluate medical workers’ and policy makers’ knowledge of ethical issues in compulsory screening particularly for disease more likely to be associated with stigma or forms of stress. The impact of integrating compulsory screening with routine diagnostic services on service uptake should be further explored.

Also, evaluating views and attitudes of close family members or partners about their kindred and spouses being diagnosed to have a potentially stigmatizing infectious disease would shed light on how to provide social and emotional support.

7.4. Study limitations

Socio-demographic details of the participants were not considered. Also, there was a small sample for the health workers and supervisors. This would require that more facilities be visited including the various levels of policy making and implementation and more vigorous interviews conducted. It was also difficult to assess any level of distress a participant may have experienced.
REFERENCES


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APPENDICES

Appendix 1: List of National and International Documents reviewed.


Appendix 4: Focus Group Discussion Guide for clients screened for Cancer of the cervix (English Version).

Appendix 5: Focus Group Discussion Guide for clients screened for Cancer of the cervix (Kiswahili Version).

Appendix 6: Questionnaire to service providers and supervisors.

Appendix 7: Informed Consent form (English and Kiswahili Versions).

Appendix 8: Thesis Proposal Approval.

Appendix 9: Ethics clearance for dissertation from UKZN.

Appendix 10: Research authorization letter from National Council of Science and Technology.

Appendix 11: Research clearance permit from National Council of Science and Technology.
Appendix 1: List of National and International Documents reviewed

1. National Reproductive Health Policy: Enhancing Reproductive Health Status for all Kenyans. 2000
2. MOH 216. Mother and child Health Booklet
4. The Kenya Public Health Act of 1986 (Cap 242),
5. Kenya Demographic Health Survey 2003 (Central Bureau of Statistics)
7. Cervical Cancer Screening in Developing Countries: report of a WHO consultation. 2002
Appendix 2:

Focus Group Discussions (FGD) Guide for Clients screened for Syphilis (English version)

Questions to Assess Client Perspectives of Screening

Thank you for agreeing to come and participate in this group discussion. We shall discuss about the issues related to testing individuals to find out whether they have signs of a given disease or chances of developing it before they become aware of it. The purpose of such a test would be to detect a disease early enough in order to plan how to manage it in time. Also, it may be a public health requirement. It is a form of disease prevention. We would like to get your views about this approach to preventing disease. The discussion will last approximately two hours. If you have further questions or need for clarification you may raise it.

Now we shall start if you are ready. First we shall introduce ourselves by our preferred names, and then go straight to the subject of our discussions. We encourage everyone to participate freely and actively, but respective each other’s opinions and giving each other time to speak.

Knowledge of the target disease

1. What do you know about Syphilis?

2. Do you think after undergoing the screening exercise, you now have a better understanding of this disease than before?

3. Do you have any concerns if you or any other person close to you could get the disease?

The concept of preventing disease and early detection

4. How would you avoid or minimize the chances of getting sick with this disease?

5. In what ways do you think investigating if someone has a certain disease could be useful to the community?

6. Ask each individual whether:

   i. She/he came purposely for the screening test (if yes – is it the first or repeat test)

   ii. She/he was aware the test was available before or was informed about it while at the clinic

   iii. She/he undertook the test only because the doctor requested for it to be done
Awareness and concerns about the disease screening services

7. What are some of the concerns that you might have about testing people for Syphilis before they are aware of the symptoms?

8. What are some of your concerns with regard to:
   a. How clients are told about and enrolled for the screening exercise?
   b. How the tests / procedures are conducted at this clinic?
   c. The information given to the clients:
      
      **Probe:**
      1. If the language used is easily understandable to them or its too technical
      2. If they are given sufficient information that makes it easier to make informed decision;
      3. If they are given any written information;
         
         Whether clients are given opportunity to participate in decision making for the tests
      d. Getting the test results:
         
         **Probe**
         1. Concerns about how their results are released to them
         2. their concerns about keeping private their records or information about their disease status,
            
            whether positive or negative;
         3. How well they are satisfied with the amount of the information they were given after the result
            (do they feel that the information was sufficient?)
         4. What more support they would need to help them cope with the test results.
         5. How they would like to be involved in making decisions about the test results

Feelings about undergoing screening

9. How did you feel about the test procedures you went through?

10. What do you feel about undergoing a repeat exam if it could help to prevent you from getting the Syphilis?
11. How do you think people close to you (e.g. spouse, family members) would feel about undergoing similar examinations to detect Syphilis?

12. How would you feel if your family members (e.g. spouse) or people close to were made aware of your test results?

Perspectives about participation in screening services

13. What in your opinion may prevent more women from coming to the clinic to be tested for Syphilis?

   [Probe]
   i. their feelings about getting positive test results indicating the presence of the disease;
   ii. their feelings about the husband or partner or family member having to approve of ones choice to be tested;
   iii. Specific concerns about:
       a) The services that are offered in this clinic;
       b) Who is providing the services;
       c) Accessing the clinic for screening or other services;
       d) Costs involved to undergo all the procedures when required to;
       e) Time spent through the procedures during visits;
       f) Being asked to come for repeat tests at a later date.

14. What would make it easier for you [for your partner] to go for the screening services for Syphilis?

   (Explore, depending on the previous answers.

Location and timing of services

15. What would you consider for a place to be the best place for you to go for the screening?

16. Do you know where else you could access these services?

Now we have come to the end of this session, unless you have any questions regarding our discussions. Thank you for your kind participation in this discussion. I hope you found it very helpful and fruitful.
Appendix 3: (Kiswahili version)

Mahojiano kwa washiriki katika uchunguzi wa mapema wa magonjwa ili kufahamu jinsi wanavyochukulia huu utaratibu wa kuzuia magonjwa

(Maswali haya ni kwa waliochunguzwa kwa ajili ya ugonjwa wa kaswende)

Tangulizi


Ufahamu wa hali ya ugonjwa

1. Je mnafahamu nini kuhusu huu ugonjwa wa kaswende?

2. Je, baada ya kupitia uchunguzi huu, unafikiri umefaidika kwa kuelewa vizuri za zaidi ya ugonjwa huu sasa ukilinganisha na hapa mbeleni?

3. Je, maoni yenzi yapi iwapo wewe, jamaa au rafiki wa karibu amepatikana na huu ugonjwa?

Uvumbuzi wa magonjwa mapema kama njia ya kuzuia maradhi

4. Tafadhali tuelezeni njia ambayo mtu anaweza kutumia kuzuia au kupunguza nafasi ya kupata huu ugonjwa

5. Mnafikiri ni kwa njia gani hatua ya kuvumbua ugonjwa kwa mapema kunaweza leta manufaa kwa wananchi?
6. Uliza kila mmoja iwapo:
   i. Alikuja mwenyewe kwa lengo la kupimwa au la (ikiwa ndio, uliza kama ni mara yake kwanza au aliagizwa kurudia kupimwa mara ingine ama kupata majibu)
   ii. Alijua kuwa kuna njia hizi za kupimwa mbeleni au aliarifiwa tu na daktari alipofika kwa kliniki.
   iii. Ilimbidi kupimwa tu kwa sababu daktari aliagiza au alionelea kwa hiari kuwa yafaa baada ya kupata maelezo kamili

Mambo yanayohusu wahusika na huduma ya kuvumbua magonjwa kwa mapema

7. Je, mna maoni gani kuhusu huduma ya kupima watu kwa ajili ya kuvumbua huu ugonjwa wa kaswende?

   [kuvumbua ugonjwa ni kumpima hali ya afya mtu anayeonokana ni mzima kusudi itambulikane mapema kama kuna dalili au uwezekano wa kuwepo kwa ugonjwa fulani ili matibabu yake na jinsi ya kuuzuia ianzishwe kwa wakati unaofaa?]

8. Je, hisia zenu ni yapi kuhusu mambo yafuatayo?
   a. Jinsi wahusika / wateja wanavyoarifiwa na kuagizwa kupimwa kwa sababu ya kuvumbwa ugonjwa uliosetirika?
   b. Jinsi huduma hii na njia za kupimwa zinavyotekelezwa kwa kliniki hii?
   c. Maelezo na mafundisho yanayopewa wahusika/wateja wanapopokea huduma hizi

   [Chunguza kwa undani]:
   i. Iwapo lugha na maelezo yanayotolewa yanaeleweka kwao kwa urahisi
   ii. Iwapo ujumbe wanaopata juu ya ugonjwa huu na huduma ilioko inawasaidia kufanya uamuzi wa hiari kuhusu hatua inayowafa wenyewe;
   iii. Kama wanahushishwa vilivyvo kuamua iwapo watapimwa
   iv. Iwapo wanapewa maelezo yaliyoandikwa au kunenewa tu;
   d. Kutolewa kwa majibu baada ya kupimwa:
[Chunguza kwa undani]

i. maoni juu ya kutolewa kwa majibu yao (yaani, jinsi inavyofanywa)

ii. Maoni yao juu ya kuweka siri hali yao ya ugonjwa kufuatia matokeo waliyopata;

iii. Hisia zao baada ya kupokea matokeo ya hali yao ya ugonjwa;

iv. Kuridhika kwao na maelezo wanayopewa baada ya kupashwa habari hizo.

v. Baadhi ya usaidizi ambayo wangehitaji kukabiliana na matokeo hayo.

vi. Wanafikiri wangehushishwa kwa njia gani gani kuhusu kutoa majibu haya?

Hisia kuhusu kupimwa kwa ajili ya kuvumbwa mapema ugonjwa uliosetirika

9. Ulikuwa na hisia gani ulipopitia hatua hizi za kupimwa?

10. Una hisia gani iwapo utaombwa urudie kupimwa mara ingine au kila baada ya muda fulani kwa sababu kuna umuhimu katika kufanya hivyo?

11. Je, mnafikiri jamaa ama marafiki zenu wanaweza kuwaamulia kupimwa jinsi ulivyojuliana ili kubainisha kuwepo kwa huu ugonjwa wa kaswende?

12. Je, ungehisi aje iwapo jamaa, mwajiri ama mbali marafiki zako watajulishwa kama kuhudhuria kliniki kwa ajili ya ugonjwa huu? [mwenyewe unweza kuwasiliana ku kliniki au kufanya maamuzi kuhusu hivi hivi]

Maoni juu ya kushiriki katika huduma ya kuvumbwa magonjwa kwa mapema

13. Je, kwa maoni yao, ni nini inaweza kuwasiliana akina mama kuhudhuria kliniki wao ajili ya kupimwa hali ya kuwasiliana?

[Chunguza kwa undani]

i. Hisia zao wakipatikana na ugonjwa huu wa kuwasiliana;

ii. Hisia zao kuwasiliana baadhi ya jamaa yao kuwaamulia kupimwa;

iii. Maoni yanayolenga yafuatayo:

   a) Huduma zinazojulikana kwa kliniki hii;

   b) Wanaotoa huduma hizi;
c) Kupata huduma hizi za kuchunguzwa magonjwa yaliyosetirika pamoja na kupata matibabu kwa kliniki hii;

d) Gharama za uchunguzi au kupimwa;

e) Muda unaochukua ukishughulikia kupimwa kila ujapo kliniki;

f) Kuulizwa kurudi mara ingine kupimwa hali yako.

14. Je, ni nini ingerahisisha kuja kwako au mwenzako kwa klinik kuchunguzwa hali ya kuwa na huu ugonjwa wa kaswende? (*hapa, chunguzwa kulingana na majjibu ya hapo awali*).

**Pahali na wakati wa kutolea huduma**

15. Ungependekeza nini kwa klinik hii ili iwe inafaa zaidi kwa huduma kama hizi za kuchunguza magonjwa yaliyosetirika?

16. Je, unajua pahali pengine pia ambapo unaweza kupokea huduma kama hizi?

Appendix 4:

Focus group discussions (FGD) Guide for Clients screened for Cancer of the cervix (English version)

Questions to Assess Client Perspectives of Screening _ FGD (focus group discussions) Guide

Thank you for agreeing to come and participate in this group discussion. We shall discuss about the issues related to testing individuals to find out whether they have signs of a given disease or chances of developing it before they become aware of it. The purpose of such a test would be to detect a disease early enough in order to plan how to manage it in time. Also, it may be a public health requirement. It is a form of disease prevention. We would like to get your views about this approach to preventing disease. The discussion will last approximately two hours. If you have further questions or need for clarification you may raise it.

Now we shall start if you are ready. First we shall introduce ourselves by our preferred names, and then go straight to the subject of our discussions. We encourage everyone to participate freely and actively, but respective each other’s opinions and giving each other time to speak.

Knowledge of the target disease

1. What do you know about Cancer of the cervix?
2. Do you think after undergoing the screening exercise, you now have a better understanding of this disease than before?
3. Do you have any concerns if you or any other person close to you could get the disease?

The concept of preventing disease and early detection

4. How would you avoid or minimize the chances of getting sick with this disease?
5. In what ways do you think investigating if someone has a certain disease could be useful to the community?
6. Ask each individual whether:
   i. She came purposely for the screening test (if yes – is it the first or repeat test)
   ii. She was aware the test was available before or was informed about it while at the clinic
   iii. She undertook the test only because the doctor requested for it to be done
Awareness and concerns about the disease screening services

7. What are some of the concerns that you might have about testing people for Cancer of the cervix (in women) before they are aware of the symptoms?

8. What are some of your concerns with regard to:
   a. How clients are told about and enrolled for the screening exercise?
   b. How the tests/procedures are conducted at this clinic?
   c. The information given to the clients:
      Probe:
      i. If the language used is easily understandable to them or its too technical
      ii. If they are given sufficient information that makes it easier to make informed decision;
      iii. If they are given any written information;
         Whether clients are given opportunity to participate in decision making for the tests
   d. Getting the test results:
      [Probe]
      i. Concerns about how their results are released to them
      ii. their concerns about keeping private their records or information about their disease status, whether positive or negative;
      iii. How well they are satisfied with the amount of the information they were given after the result (do they feel that the information was sufficient?)
      iv. What more support they would need to help them cope with the test results.
      v. How they would like to be involved in making decisions about the test results

Feelings about undergoing screening

9. How did you feel about the test procedures you went through?

10. What do you feel about undergoing a repeat exam if it could help to prevent you from getting the Cancer of the cervix (for women only)?
11. How do you think people close to you (e.g. spouse, family members) would feel about undergoing similar examinations to detect Cancer of the cervix?

12. How would you feel if your family members (e.g. spouse) or people close to you were made aware of your test results?

**Perspectives about participation in screening services**

13. What in your opinion may prevent more women from coming to the clinic to be tested for Cancer of the cervix?

   [Probe]

   i. their feelings about getting positive test results indicating the presence of the disease;

   ii. their feelings about the husband or partner or family member having to approve of one’s choice to be tested;

   iii. Specific concerns about:

      a) The services that are offered in this clinic;

      b) Who is providing the services;

      c) Accessing the clinic for screening or other services;

      d) Costs involved to undergo all the procedures when required to;

      e) Time spent through the procedures during visits;

      f) Being asked to come for repeat tests at a later date.

14. What would make it easier for you [for your partner] to go for the screening services for Cancer of the cervix? (Explore, depending on the previous answers.

**Location and timing of services**

15. What would you consider for a place to be the best place for you to go for the screening?

16. Do you know where else you could access these services?

Now we have come to the end of this session, unless you have any questions regarding our discussions. Thank you for your kind participation in this discussion. I hope you found it very helpful and fruitful.
Appendix 5: (Kiswahili version)

Mahojiano kwa washiriki katika uchunguzi wa mapema wa magonjwa ili kufahamu jinsi wanavyochukulia huu utaratibu wa kuzuia magonjwa

(Maswali haya ni kwa waliochunguzwa kwa ajili ya saratani ya sehemu ya uke)

Tangulizi


Ufahamu wa hali ya ugonjwa

1. Je mnafahamu nini kuhusu huu ugonjwa wa kansa ya sehemu ya uke?
2. Je, baada ya kupitia uchunguzi huu, unafikiri umefaidika kwa kuelewa vizuri zaidi hali ya ugonjwa huu sasa ukilinganisha na hapo mbeleni?
3. Je, maoni yenu ni yapi iwapo wewe, jamaa au rafiki wa karibu amepatikana na huu ugonjwa?

Uvumbuzi wa magonjwa mapema kama njia ya kuzuia maradhi

4. Tafadhali tuelezeni njia ambayo mtu anaweza kutumia kuzuia au kupunguza nafasi ya kupata huu ugonjwa
5. Mnafikiri ni kwa njia gani hatua ya kuvumbua ugonjwa kwa mapema kunaweza leta manufaa kwa wananchi?

6. Uliza kila mmoja iwapo:
   i. Alikuja mwenyewe kwa lengo la kupimwa au la *(ikiwa ndio, uliza kama ni mara yake kwanza au aliagizwa kurudia kupimwa mara ingine ama kupata majibu*)
   ii. Alijua kuwa kuna njia hizi za kupimwa mbeleni au aliarifiwi tu na daktari alipofika kwa kliniki.
   iii. Ilimbidi kupimwa tu kwa sababu daktari aliagiza au alionelea kwa hiari kuwa yafaa baada ya kupata maelezo kamili

**Mambo yanayohusu wahusika na huduma ya kuvumbua magonjwa kwa mapema**

7. Je, mna maoni gani kuwahusu huduma ya kupima watu kwa ajili ya kuvumbua huu ugonjwa wa kansa ya sehemu ya uke?

   *[kuvumbua ugonjwa ni kumpima hali ya afya mtu anayeonokana ni mzima kusudi itambulikane mapema kama kuna dalili au uwezekano wa kuwepo kwa ugonjwa fulani ili matibabu yake na jinsi ya kuuzuia ianzishwe kwa wakati unaofaa]*)?

8. Je, hisia zenu ni yapi kuwahusu mambo yafuatayo?
   a. Jinsi wahusika / wateja wanavyoarifiwa na kuagizwa kupimwa kwa sababu ya kuvumbwa ugonjwa uliosetirika?
   b. Jinsi huduma hii na njia za kupimwa zinavyotekelezwa kwa kliniki hii?
   c. Maelezo na mafundisho yanayopewa wahusika/wateja wanapopokea huduma hizi

   *[Chunguza kwa undani]:*
      i. Iwapo lugha na maelezo yanayotolea yanaeleweka kwao kwa urahisi
      ii. Iwapo ujumbe wanaopata juu ya ugonjwa huu na huduma ilioko inawasaidia kufanya uamuzi wa hiari kuhusu hatua inayowafaa wenyewe;
iii. Kama wanahushihwa vilivyokuamua iwapo watapimwa

iv. Iwapowanapewamaelezo yaliyoandikwa au kunenewatu;

d. Kutolewa kwa majibu baada ya kupimwa:

[Chunguza kwa undani]

i. Maonijuu ya kutolewa kwa majibu yao (yaani, jinsi inavyofanywa)

ii. Maoni yao juu ya kuweka siri hali yao ya ugonjwa kufuatia matokeo waliyopata;

iii. Hisia zao baada ya kupokea matokeo ya hali yao ya ugonjwa;

iv. Kuridhika kwao na maelezo wanayopewa baada ya kupashwa habari hizo.

v. Baadhi ya usaidizi ambayo wangehitaji wangehitaji kukabiliana na matokeo hayo.

vi. Wanafikiri wangehushishwa kwa njia gani kuwa mahfata kutoa majibu haya?

Hisia kuhusu kupimwa kwa ajili ya kuvumbwa mapema ugonjwa uliosetirika

9. Ulikuwa na hisia gani ulipopitia hatua hizi za kupimwa?

10. Una hisia gani iwapo utaombwa urudie kupimwa maringine au kila baada ya muda fulani kwa sababu kuna umuhimu katika kufanyanya hivyo?

11. Je, mnafikiri jamaa ama marafiki zenu wanaweza kuwa radhi kupimwa jinsi ulivyotendewa ili kubainisha kuvumwa kwa hali ya ugonjwa wa kansa ya sehemu ya uke?

12. Je, ungehisi aje iwapo jamaa, mwajiri ama hata marafiki zako watajulishwa hali ya ugonjwa huu? [mwenye wewe kuwa kwishirikia watu wao kwenye katika kuvumbwa mali ya uke]

Maoni juu ya kushiriki katika huduma ya kuvumbwa magonjwa kwa mapema

13. Je, kwa maoni yako, ni nini inaweza kuzua akina mama kuhudhuria kliniki kwa ajili ya kupimwa hali ya kansa ya sehemu ya uke?

[Chunguza kwa undani]

i. Hisia zao wajulisha na ugonjwa huu wa kansa ya sehemu ya uke;
ii. Hisia zao kuhusu baadhi ya jamaa yao kuwaamulia kupimwa;

iii. Maoni yanayolenga yafuatayo:
   a) Huduma zinazotolewa kwa kliniki hii;
   b) Wanaotoa huduma hizi;
   c) Kupata huduma hizi za kuchunguzwa magonjwa yaliyosetirika pamoja na kupata matibabu kwa kliniki hii;
   d) Gharama za uchunguzi au kupimwa;
   e) Muda unaochukua ukishughulikia kupimwa kila ujapo kliniki;
   f) Kuulizwa kurudi mara ingine kupimwa hali yako.

14. Je, ni nini ingerahisisha kuja kwako au mwenzako kwa klinik kuchunguzwa hali ya kuwa na huu ugonjwa wa kansa ya sehemu ya uke? (hapa, chunguza kulingana na majjibu ya hapo awali).

Pahali na wakati wa kutolea huduma

15. Ungependekeza nini kwa klinik hii ili iwe inafaa zaidi kwa huduma kama hizi za kuchunguza magonjwa yaliyosetirika?

16. Je, unajua pahali pengine ambapo unaweza kupokea huduma kama hizi?

Appendix 6: Policy Decision Issues: Questionnaire to the policy-makers and health managers/providers

1. How do the screening programs fit in the overall health sector strategic plan?

_______________________________________________________________________________________
_______________________________________________________________________________________
_______________________________________________________________________________________
_______________________________________________________________________________________
_______________________________________________________________________________________

2. Is there a comprehensive national plan for screening as a public health preventive strategy and what are the main objectives?

_______________________________________________________________________________________
_______________________________________________________________________________________
_______________________________________________________________________________________
_______________________________________________________________________________________
_______________________________________________________________________________________

3. Is there a single national body that reviews screening practice and policy, population registers for recall and follow up of patients or does the ministry work through an advisory committee? [Answer question 4 if the answer to this is yes]

_______________________________________________________________________________________

4. How is it administered in terms of:
   a. Administrative structure

_______________________________________________________________________________________
_______________________________________________________________________________________
_______________________________________________________________________________________
_______________________________________________________________________________________

   b. Budget and financing

_______________________________________________________________________________________
_______________________________________________________________________________________
_______________________________________________________________________________________
_______________________________________________________________________________________

   c. Specific national guidelines and regulations applicable

_______________________________________________________________________________________
_______________________________________________________________________________________
_______________________________________________________________________________________
_______________________________________________________________________________________

   d. Standards and quality control [Explain if there are specific GUIDELINES available for Cancer of the cervix and Syphilis]

_______________________________________________________________________________________
_______________________________________________________________________________________
_______________________________________________________________________________________
_______________________________________________________________________________________

5. How are the considerations (a–f) used to approve screening programs applicable to screening of Cancer of the cervix and Syphilis in Kenya? (see table 1 below)
a. Medical / epidemiological considerations
   i. How common the disease is [i.e. Common or rare but serious and treatable]?

   ii. Can the population that needs treating be clearly defined, and called for screening?

   iii. Availability of a valid and repeatable screen test [in terms of sensitivity; specificity and repeatability]:

   iv. Lead time advantage [Lead time is defined as the time by which screening advances diagnosis or survival time since diagnosis]

   v. Treatment for the condition

   vi. Effect of screening on uptake of treatment services for Cancer of the cervix and / or Syphilis.

   vii.

b. Procedural considerations
   i. Are facilities for diagnosis and treatment available [e.g. Availability of the test kit]?

   ii. Are there regular quality control procedures undertaken?

   iii. Is the space available appropriate to guarantee safety and privacy of clients?

   iv. Lead time advantage [Lead time is defined as the time by which screening advances diagnosis or survival time since diagnosis]

   v. Treatment for the condition

   vi. Effect of screening on uptake of treatment services for Cancer of the cervix and / or Syphilis.

   vii.

c. Legal considerations
   i. Protection against infringement of the civil liberties of the individual vis-a-vis the potential benefits of carrying out the exercise [in terms of the legal provisions e.g. of the public health act].

   ii. Institutions allowed to carry out these tests [public only or even private health institutions?]
d. Ethical considerations
   i. acceptability of the test to the population;

   ii. availability and accessibility of the test;

   iii. continuous follow up of clients rather than a "once and for all" project;

   iv. an agreed policy on who to treat and referrals

   v. Ensuring comprehensiveness and confidentiality of the information provided

e. Economic considerations [in relation to the following];
   i. Has the cost of the programme been considered in the context of other demands for resources [Explain briefly]?

   ii. The total cost of finding a case compared to the mortality outcomes

   iii. Is the programme affordable (opportunity cost must be considered)?

   iv. Is the programme subject to quality assurance?

f. Other considerations
   i. What is the public health impact of the disease if not diagnosed early?
Table 1: Experience with Screening Programs for Syphilis (at ANC visits) and Cancer of the cervix in Kenya

<table>
<thead>
<tr>
<th>Target Screening Program</th>
<th>Background Description of the program</th>
<th>Decision criteria (Medical, Procedural, Legal, Ethical, Economic, Other considerations) – main considerations to implement the program</th>
<th>Time frame: moving from DECISION to OPERATING POLICY to IMPLEMENTATION of program – where are we in terms of implementing the program</th>
<th>Current status of the screening program – is it ongoing nationally or only in selected areas</th>
<th>Classify screening program (Mandatory; Routine or Voluntary)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SYPHILIS</td>
<td></td>
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<td></td>
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<tr>
<td>CANCER OF THE CERVIX</td>
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<td></td>
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</tbody>
</table>
6. Overall Assessment and Rating of Strength of Recommendations and Quality of Evidence* (for the specific screening programs):

a. Table 1: Rating of Strength of Recommendations (for each screening program)*.

<table>
<thead>
<tr>
<th>Rating</th>
<th>Comments</th>
<th>Remarks / target disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Good evidence to support</td>
<td>Syphilis</td>
</tr>
<tr>
<td>B</td>
<td>Fair evidence to support</td>
<td>Cancer of the cervix</td>
</tr>
<tr>
<td>C</td>
<td>Insufficient evidence to recommend for or against</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>Fair evidence against</td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>Good evidence against</td>
<td></td>
</tr>
</tbody>
</table>

b. Table 2: Rating for quality of evidence* *(Tick the applicable rating)*

<table>
<thead>
<tr>
<th>Rating</th>
<th>Comments / interpretation of rating</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Evidence from at least one randomized controlled trial</td>
<td></td>
</tr>
<tr>
<td>II-1</td>
<td>Evidence from controlled trials without randomization</td>
<td></td>
</tr>
<tr>
<td>II-2</td>
<td>Evidence from cohort or case-control studies</td>
<td></td>
</tr>
<tr>
<td>II-3</td>
<td>Evidence from multiple time series or historic controls</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>Expert opinion based on clinical experience</td>
<td></td>
</tr>
</tbody>
</table>

7. Measures of Screening Effectiveness

Table 3: Measures of effectiveness of Screening*

*(Evaluate each variable 1 – 6 on the scale provided. Place a tick in the applicable box)*

<table>
<thead>
<tr>
<th>Measures of Screening</th>
<th>Rating (place tick)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low 1</td>
</tr>
<tr>
<td>1 Relative risk and relative risk reduction</td>
<td></td>
</tr>
<tr>
<td>2 Gain in life expectancy</td>
<td></td>
</tr>
<tr>
<td>3 Cost per case detected</td>
<td></td>
</tr>
<tr>
<td>4 Cost per life saved</td>
<td></td>
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<tr>
<td>5 Gain in quality-adjusted life years (QALYs)</td>
<td></td>
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<tr>
<td>6 Number needed to screen (NNS)</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 7: Informed Consent Form for Clients

University of KwaZulu-Natal
Faculty of Humanities, Development and Social Sciences
School of Psychology
South African Research Ethics Training Initiative (SARETI)
Pietermaritzburg Campus

Title of Study
SCREENING POPULATIONS FOR DISEASE IN KENYA: FRAMEWORKS FOR POLICY DECISIONS AND THE PARTICIPANTS’ PERSPECTIVES.

Dear Sir/Madam,
You are invited to participate in this research study, which is part of my training towards the degree of Master of Social Science (Health Research Ethics) at the University of KwaZulu Natal in South Africa. The study aims to explore the perceptions of stakeholders (specifically policy makers/health managers and clients who use the services) on screening (screening include special methods and tests which the physician or other health worker may use to detect a disease before its symptoms appear). Specifically I would like to ask you more about the way you feel about this method of looking for disease before it manifests from your experience.

You have been invited to participate because you have undergone the whole procedures / tests. The medical staff who examined you knows about the study and would discuss with their clients about the study and the possibility of referring to us. If you agree to participate, you will be taking part in a group discussion with a few more people who have similarly been tested. This will help us understand more clearly how people who are invited for testing generally feel about the screening process.

This process will last for about two hours or less. A short snack will be served while we discuss but there will be no reimbursements for your fares or other monetary compensations. Your participation will be entirely voluntary and you may withdraw at any stage if you so wish. Everyone’s contributions will be treated as important.

During the discussion, if you find particular questions or responses from others to be emotionally stressful, kindly let us know at any point when you feel so. Also, your voices will be recorded during the whole session. This is a recommended technique for this method of interview in order to help us not lose any information during analysis. However this is only for the purpose of the session and will not be publicized in any way or be related to your person during reporting. All information is confidential and nobody else will handle or see what you tell us here, except for the written report, but which shall not relate to you identity.

Please ask for further clarifications about the study from any of the undersigned if need be. You will be given a copy of this form to keep, while the investigator will also keep a copy. Contact details are included.

______________________________                                                         _______________________
Signature of client / thumb print       Date

Contact Address: 1) Dickens S. Omondi Aduda.
Impact Research and Development OrganizationBox
849. Kisumu.
Tel. 0722385291 / 0738699524
Email: omondisda@yahoo.com

Signature:
Date: ____________________________

2) Prof. N. Mkhize.
Tel. +27 33 2605963; +27 33 2605853
Email: mkhize@ukzn.ac.za

Date: ____________________________
SCREENING POPULATIONS FOR DISEASE IN KENYA: FRAMEWORKS FOR POLICY DECISIONS AND THE PARTICIPANTS’ PERSPECTIVES.

Kwako mpendwa,

Umealikwa kushiriki katika utafiti huu kwa sababu umepitia huduma hii ya kuchunguzwa. Daktari au muunguzi aliyekuona ameelezwa juu ya utafiti huu ndiyo sababu alikuarufu na ubora ujuzi wa kuchunguzwa wako. Kama utakubali kushiriki, utajinya na wengine sita na saba waliopita katika utafiti huu kwa nje wa uchunguzi wa watu wanaoishi katika sera za kutoa huduma za afya. Wengine pia watashirikishwa katika sehemu mbalimbali. Sababu ya hii ni kutuwezesha kupata maoni mbalimbali kwa jumla ili kutoa huduma za afya katika ushauri wa watu wanaoishi.


Sahihi ya mshiriki
Tarehe

<table>
<thead>
<tr>
<th>Anwani</th>
<th>Tarehe</th>
</tr>
</thead>
<tbody>
<tr>
<td>2) Prof. N. Mkhize. Simu. +27 33 2605963; +27 33 2605853 Barua pepe: <a href="mailto:mkhize@ukzn.ac.za">mkhize@ukzn.ac.za</a></td>
<td></td>
</tr>
</tbody>
</table>
We are satisfied with the academic merit and viability of the research project.

Date: 18/1/08

[Signature]

Student Signature

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Masters Degree Research Proposal

Faculties of Humanities, Development and Social Sciences

KwaZulu-Natal

University of

---

[Signature]

Student Name: Dicky Samuk Qhumbu Andile (209529830)

Discipline: Psychology

School: W. soc sc (Research Ethics)

Proposal: W. SOC SC (research ethics)

Research Article: 25% 10000 words 48 credits

Thesis: 33.3% 14 000 words 64 credits

Short Dissertation: 20 000 words 50 credits

Conversion/Thesis: 66.6% 28 000 words 128 credits

Dissertation: 100% 40 000 words 192 credits

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The final year of the coursework: Psychology (electronic)

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Updated at 24 October 2006
15 April 2009

UKZN
School of Psychology

Policy Decisions and the Participation: Perspectives
Screening Populations for Disease in Kenya: Frameworks for
Research and Practice.

Re: Ethical Clearance for Masters Dissertation Research

Dear Mr. Dickens S. Aduda Omondi,
Appendix 10: Research Authorization Letter from National Council of Science and Technology

Republic of Kenya

National Council for Science and Technology

Telegram: "SCINETECH", Nairobi
Telephone: 254-020-241349, 2213102
254-020-310571, 2213123
Fax: 254-020-2213215, 318245, 318249
When replying please quote

Ref: NCST/5/002/R/152/5

Date: 19th May 2009

Mr. Dickens Omondi
University of Kwa Zulu - Natal
SOUTH AFRICA

RE: RESEARCH AUTHORIZATION

Following your application for authority to carry out research on, Screening Populations for Disease in Kenya: Frameworks for Policy Decisions and the Participants' Perspectives'

I am pleased to inform you that you have been authorized to carry out research in Kisumu East District for a period ending 30th December 2009.

You are advised to report to the District Commissioner and the Medical Officer of Health, Kisumu East District before embarking on your research.

On completion of your research, you are expected to submit two copies of your research report to this office.

PROF. S. A. ABDULRAZAK Ph.D, MBS
SECRETARY

Copy to:
The District Commissioner
Kisumu East District

The Medical Officer of Health
Kisumu East District
THIS IS TO CERTIFY THAT: OMONDI DICKENS
of (Address) UNIVERSITY OF KWA ZULU NATAL, SOUTH AFRICA
has been permitted to conduct research in KISUMU EAST District,
NYANZA Province, SCREENING POPULATIONS FOR DISEASE IN KENYA: FRAMEWORKS FOR POLICY DECISIONS AND THE PARTICIPANTS' PERSPECTIVES'
for a period ending 30TH DECEMBER, 2009.

CONDITIONS

1. You must report to the District Commissioner and the District Education Officer of the area before embarking on your research. Failure to do that may lead to the cancellation of your permit.
2. Government Officers will not be interviewed without prior appointment.
3. No questionnaire will be used unless it has been approved.
4. Excavation, filming and collection of biological specimens are subject to further permission from the relevant Government Ministries.
5. You are required to submit at least two(2)/four(4) bound copies of your final report for Kenyans and non-Kenyans respectively.
6. The Government of Kenya reserves the right to modify the conditions of this permit including its cancellation without notice.

Research Permit No. NCST/5/002/R/152
Date of issue 19.5.2009
Fee received SHS. 1000.00

Applicant's Signature

Secretary National Council for Science and Technology
This is to certify that:
Prof/Dr/Mr./Mrs./Miss. OMONDI DICKENS
of (Address) UNIVERSITY OF KWA ZULU NATAL, SOUTH AFRICA
has been permitted to conduct research in:
Location, KISIMU EAST District,
NYANZA Province,
on the topic: SCREENING POPULATIONS FOR DISEASE IN KENYA: FRAMEWORKS FOR POLICY DECISIONS AND THE PARTICIPANTS' PERSPECTIVES'
for a period ending: 30TH DECEMBER 2009

Research Permit No.: NCST/5/002/R/152
Date of issue: 19.5.2009
Fee received: SHS.1000.00

[Signature]
Applicant's Signature

[Signature]
Secretary
National Council for Science and Technology
CONDITIONS

1. You must report to the District Commissioner and the District Education Officer of the area before embarking on your research. Failure to do that may lead to the cancellation of your permit.
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6. The Government of Kenya reserves the right to modify the conditions of this permit including its cancellation without notice.

GPK 6055—3m—10/2009

(CONDITIONS—see back page)
Appendix 11: Research Clearance Permit from National Council of Science and Technology

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**CONDITIONS**

1. You must report to the District Commissioner and the District Education Officer of the area before embarking on your research. Failure to do that may lead to the cancellation of your permit.
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4. Excavation, filming and collection of biological specimens are subject to further permission from the relevant Government Ministries.
5. You are required to submit at least two(2)/four(4) bound copies of your final report for Kenyans and non-Kenyans respectively.
6. The Government of Kenya reserves the right to modify the conditions of this permit including its cancellation without notice.